Complaint to TGA: Pharmacare Laboratories Promensil Menopause products

This is a high priority complaint to test the TGA's will to act on recalcitrant sponsors of complementary medicines.

These products (initially sponsored by Novogen Limited but more recently by Pharmacare Laboratories) have had six complaints upheld by the now abolished Therapeutic Goods Advertising Complaint Resolution Panel (CRP) from 2000 to 2017, see: http://tgacrp.com.au/complaint-register/?_search=Promensil.

The most recent complaints (2017/10/005) and (2015/09/018) involved Pharmacare Laboratories and both determinations were referred to the Secretary for failure to withdraw misleading representations. I have appended the latest CRP determination 2017/10/005. I can find no information on the TGA website as to the outcome of these referrals.

Regardless, these products continue to be advertised with claims that have been repeatedly judged to be misleading and deceptive.

Furthermore, Pharmacare Laboratories has the unenviable reputation of the having the most upheld complaints of any sponsor of complementary medicines over the life of the CRP.

I submit that this complaint is "high priority" because the sponsor is recalcitrant, the product has had numerous upheld complaints and the varied advertising claims by the sponsor (and many others) continue to state or imply that that these products will significantly reduce the severity and frequency of menopausal symptoms when they will not.

The products involved (ARTG Public Summary Documents downloaded today appended) are:

- ARTG ID: 151247 Product name: Promensil Menopause
  Active ingredients: Trifolium pratense
- ARTG ID: 154445 Product name: Promensil Menopause Double Strength
  Active ingredients: Trifolium pratense
- ARTG ID: 288443 Product name: Promensil Women's Health
  Active ingredients: colecalciferol, concentrated fish Omega-3 triglycerides, lutein, Tagetes erecta, Trifolium pratense, ubidecarenone

I allege the promotion of these products contains (repeated) breaches of the Therapeutic Goods Advertising Code 2017, sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(f) and 4(4). These clearly impact on the consumers ability to appropriately use the good in line with their intended purpose.

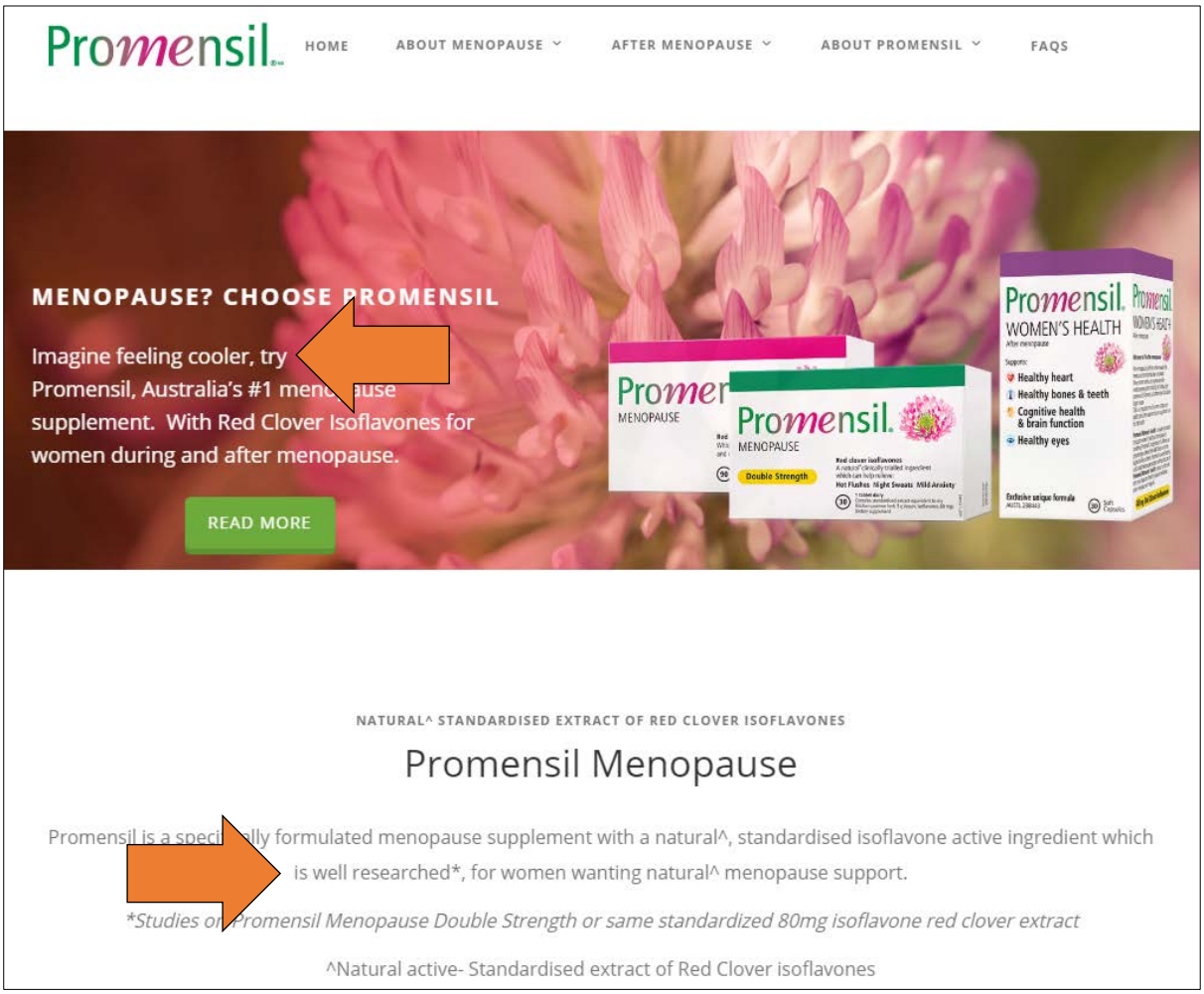
In addition, current specific indications on the ARTG Public Summary Documents are equally misleading and deceptive, for example:

- ARTG ID: 154445:

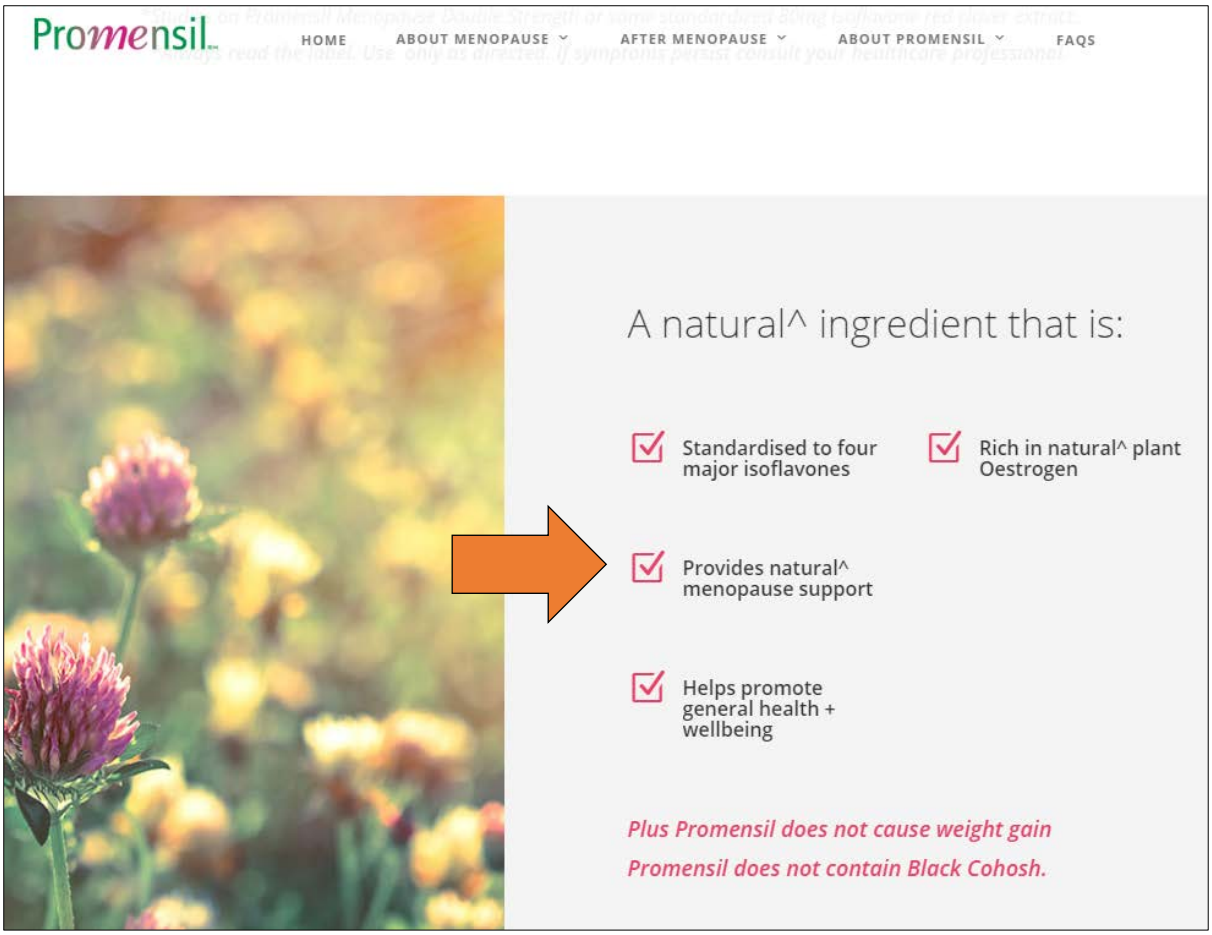
  “Extensive/The latest Clinical studies/ on /standardized/Redclover Isoflavones 80mg/ found a significant reduction in the severity and frequency of: Hot flushes by 73%/5-83%/, Night sweats by 72%/62.3-71.3%/, Relief from Mild Anxiety by 76%/ a reduction in overall menopause symptoms of 68.7%/Promotes wellbeing/Feel cooler/Promensil is a specifically formulated menopause supplement with a natural, standardized /80mg/ isoflavone active ingredient which is backed by 12 years of /international/scientific research*, for women wanting natural menopause support/provides /healthy/ menopause support / helps relieve symptoms of menopause/during and beyond menopause/*Lipovac M, Effect of red clover isoflavone supplementation over vasomotor and menopausal symptoms in postmenopausal women. Gynecological Endocrinology 2011;1-5 Hildago. The effect of red clover isoflavones

on menopausal symptoms, lipids and vaginal cytology in menopausal women: A randomized DBPCT study. Gynecological Endocrinology 2005;21(5):257-264. Tice Phytoestrogen Supplements for Hot Flushes: The Isoflavone Clover Extract (ICE) Study. JAMA, July 9, 2003 ± Vol 290, No. 2.//provides a high dose of active ingredient as an additional dietary support/May help maintain healthy bones in post menopausal women **/**in conjunction with adequate dietary calcium and Vitamin D/May boost daily healthy phytoestrogen levels."

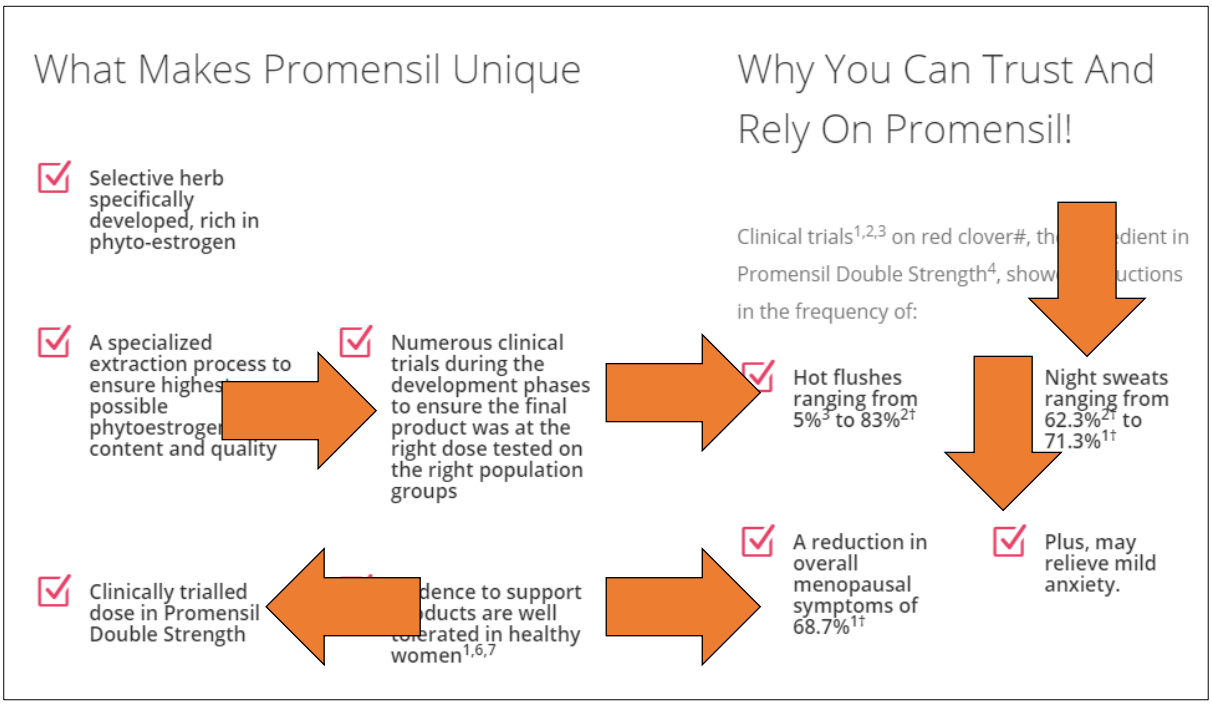
Screen shots of misleading and deceptive advertising claims taken today (06/07/2018) follow. The arrows point out ongoing claims that CRP determination 2017/10/005 agreed breached the Therapeutic Goods Advertising Code 2015.



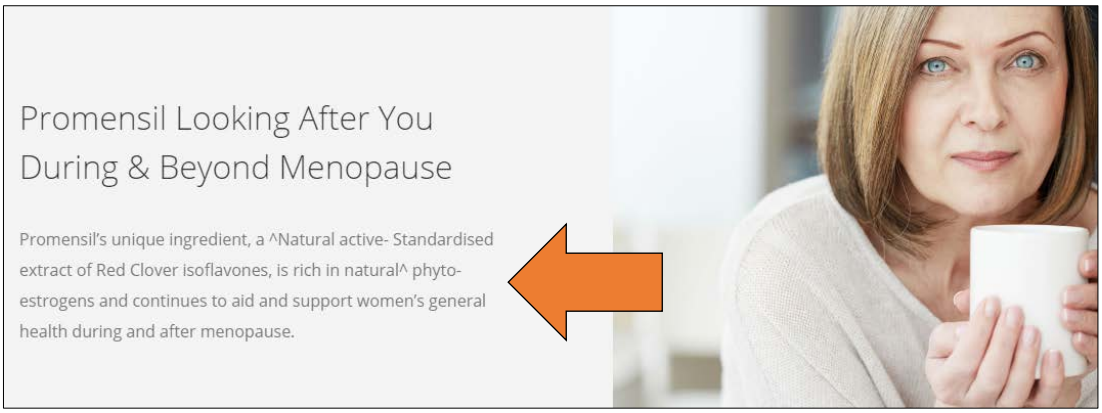
https://www.promensil.com.au/



https://promensil.com.au/about-promensil/



https://www.promensil.com.au/about-promensil/



https://promensil.com.au/about-promensil/

See also claims at:

- https://chemistwarehouse.com.au/buy/31005/Promensil-Menopause-90-Tablets
- https://discountdrugstores.com.au/promensil-double-strength-30-tablets-62538.html
- https://pharmacyonline.com.au/promensil-menopause-double-strength-tab-x-30
- https://vitaminking.com.au/promensil-menopause-double-strength-60-tablets-by-promensil
- https://health365.com.au/promensil-tabs-30s
- https://pharmacy4less.com.au/promensil-menopause-double-strength-tabx-30-3.html
- Etc.

I note that the recently enacted Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018 that states that,

> "The following specified kinds of therapeutic goods information **may** be released by the Secretary to the public under subsection 61(5C) of the Act….".

Regardless, I insist on an immediate response to me as to the priority allocated to this complaint, the measures taken by the TGA to achieve compliance and the final outcome.

Sincerely,
Ken

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6 July 2018

Public Summary

Summary for ARTG Entry: 151247 Promensil Menopause

ARTG entry for	Medicine Listed
Sponsor	Pharmacare Laboratories Pty Ltd
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia
ARTG Start Date	28/03/2008
Product category	Medicine
Status	Active
Approval area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1. Promensil Menopause

Product Type Single Medicine Product **Effective date** 1/05/2012

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Aids, assists or helps in the maintenance of general well-being

May assist in the management of menopause. [Warning S required]

Relief of menopausal symptoms. [Warning S required]

Relief of hot flushes associated with menopause. [Warning S required]

Specific Indications

Isoflavones are a group of plant compounds found mainly in legumes; including red clover, chickpeas, beans and lentils. Red clover contains isoflavones which are phytoestrogens (natural plant oestrogens).
Research has identified four principle dietary isoflavones: biochanin A, formononetin, daidzein and genistein. Red clover, unlike many other legumes, contains all four of these isoflavones.
Promensil Menopause contains 40 mg of a standardised ratio of four isoflavones in every tablet. Promensil Menopause contains a standardised 40 mg of isoflavones in every tablet.
Research has shown that increasing your intake of isoflavones (natural plant oestrogen) can help reduce menopause symptoms.
To help relieve hot flushes and night sweats.
Helps manage hot flushes and night sweats of menopause.
Helps reduce the severity and frequency of menopausal hot flushes.
Helps relieve menopausal symptoms, hot flushes, night sweats and mild anxiety and night sweats.
May help relieve anxiety.
Research has shown that in cultures consuming a diet abundant in isoflavones (phytoestrogens) women have fewer menopausal symptoms.
Research has shown that increasing your intake of isoflavones (natural plant oestrogen) can help reduce menopause symptoms.

Does not cause weight gain.

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1. Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Trifolium pratense	**100 mg**
Equivalent: Trifolium pratense (Dry)	2.5 g

Public Summary

Summary for ARTG Entry: 154445 Promensil Menopause Double Strength

ARTG entry for	Medicine Listed
Sponsor	Pharmacare Laboratories Pty Ltd
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia
ARTG Start Date	8/08/2008
Product category	Medicine
Status	Active
Approval area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1. Promensil Menopause Double Strength

Product Type Single Medicine Product **Effective date** 19/10/2015

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Relief of hot flushes associated with menopause. [Warning S required]

May assist in the management of menopause. [Warning S required]

Relief of menopausal symptoms. [Warning S required]

Aids, assists or helps in the maintenance of general well-being

Specific Indications

To help relieve hot flushes and night sweats/ Helps manage hot flushes and night sweats of menopause/ To help /Helps relieve menopausal Symptoms including hot flushes, night sweats and mild anxiety / naturally/May help relieve mild anxiety due to menopausal changes/ To help relieve dry skin/For during and after menopause/
Helps reduce the severity and frequency of menopausal hot flushes and night sweats / Natural & clinically trialled Promensil/Formula/, a patented/red clover isoflavone/ formula, with specific clinically trialled isoflavone content. / Does not cause weight gain.
Research has shown that in cultures consuming a diet abundant in isoflavones (phytoestrogens) women have fewer menopausal symptoms. Research has shown that increasing your intake of/red clover/ isoflavones (natural plant oestrogen) can help reduce menopause symptoms.
Extensive/The latest Clinical studies/ on /standardized/Redclover Isoflavones 80mg/ found a significant reduction in the severity and frequency of: Hot flushes by 73%/5-83%/, Night sweats by 72%/62.3-71.3%/, Relief from Mild Anxiety by 76%/ a reduction in overall menopause symptoms of 68.7%/Promotes wellbeing/Feel cooler/Promensil is a specifically formulated menopause supplement with a natural, standardized /80mg/ isoflavone active ingredient which is backed by 12 years of /international/scientific research*, for women wanting natural menopause support/provides /healthy/ menopause support / helps relieve symptoms of menopause/during and beyond menopause/*Lipovac M, Effect of red clover isoflavone supplementation over vasomotor and menopausal symptoms in postmenopausal women. Gynecological Endocrinology 2011;1-5 Hildago. The effect of red clover isoflavones on menopausal symptoms, lipids and vaginal cytology in menopausal women: A randomized DBPCT study. Gynecological Endocrinology

2005;21(5):257-264.
Tice Phytoestrogen Supplements for Hot Flushes: The Isoflavone Clover Extract (ICE) Study. JAMA, July 9, 2003 ± Vol 290, No. 2.//provides a high dose of active ingredient as an additional dietary support/May help maintain healthy bones in post menopausal women **/**in conjunction with adequate dietary calcium and Vitamin D/May boost daily healthy phytoestrogen levels.

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	**Poison Schedule**
Components	
1. Formulation 1	
Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	
Active Ingredients	
Trifolium pratense	**200 mg**
Equivalent: Trifolium pratense (Dry)	5 g

Public Summary

Summary for ARTG Entry: 288443 Promensil Women's Health

ARTG entry for	Medicine Listed
Sponsor	Pharmacare Laboratories Pty Ltd
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia
ARTG Start Date	1/05/2017
Product category	Medicine
Status	Active
Approval area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1. Promensil Women's Health

Product Type Single Medicine Product **Effective date** 19/05/2017

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

· Welcome to life after menopause/Post-menopause is defined as the time after the menopause transition has been completed. Many women continue to experience milder menopause symptoms including hot flushes, night sweats and mild anxiety as hormone level fluctuations/changes/begin to ease/including the natural decline of oestrogen associated with the ageing process. This is an important time for women to top up on/boost/ additional nutrients and continue to support and care for their health/wellbeing.
· The product is uniquely formulated to/help/support women's health post-menopause, by combining Promensil's unique dose of isoflavones, a phytoestrogen derived from Red Clover, with/other supportive/key/nutrients/to help specifically support post-menopausal health.
· Promensil is a world leading and trusted menopause symptom relief product, so let Promensil Women's Health continue to help look after/support/your/important health needs and/wellbeing, post-menopause and beyond.
· Helps support*: Healthy post menopause symptoms, associated with mild, easing hot flushes, night sweats and mild anxiety/*Boosting daily intake of phytoestrogens in healthy post menopause, to help support general health and wellbeing.
· Helps relieve mild/moderate menopause symptoms including hot flushes, night sweats and mild anxiety.
· General wellbeing
· The product contains 40mg of the clinically trialed ingredient Red Clover isoflavones, a natural plant oestrogen source, and is/an exclusive unique formula/ uniquely/specifically/formulated to/help/support/bone health, heart health, your active brain and eye health.
· After menopause, some women may still experience mild menopause symptoms due to the easing of hormone changes, including the natural progression towards the decline of oestrogen. As a result, during this important phase of life women may decide to focus on their changing health needs, including supporting a healthy heart, bones, eyes and brain.
· The product/is uniquely formulated to/ help(s)/support/changing health needs/women's health/and wellbeing after menopause and beyond/as hormone changes ease.

· Healthy/Bone(s)/health/After menopause, maintaining healthy bone density is important/key/to support bone health. The product contains bone-friendly Vitamin D to help/support/assist/calcium absorption to/help/support(s)/strong/healthy bones and teeth.
· Heart Health/Maintaining/supporting/a healthy/heart/health is/key/important/necessary/to support/ to/post-menopausal wellbeing, as the decline in natural oestrogen levels is associated with the ageing process. Aiding/supporting /heart/cardiovascular/health during this time is particularly important to help support cardiovascular wellness. The good news is that/ the product contains nutrients CoQ10, and Omega-3 DHA & EPA to help support heart health.
· Your Active Brain/After menopause, maintaining/supporting/healthy/brain and memory function, and cognitive health is important/to maintaining an active lifestyle/as we age to keep up with the active grand kids, the garden and our favourite past times. The product is formulated with EPA & DHA, key nutrients to help support your cognitive health and brain function/as you age.
· Eye Health/Lutein and Zeaxanthin are important carotenoids and antioxidants that help support macular and visual health which becomes a focus,/after menopause and as we age/it's important to consider our macular and visual health. It is essential in today's era/with increased use of smartphones, ipads, TV and computers/laptops,/the need to filter blue light is important/ occurs on a regular basis. Therefore, supporting healthy eye function is important. Formulated with antioxidants Lutein and Zeaxanthin, Promensil Women's Health helps support healthy/eyesight/eyes/as we age/including/and/macular health.
· Golden years? More like the action years! The product is an amazing formulation that understands women's health after menopause- and what we need to help keep us healthy.
· Like caring for my:
Bone(s)/health/to/help/keep me/moving/active/to help support my mobility.
Brain/health/to/help/keep me thinking/support/maintain/healthy/my/memory and brain function.
Eye(s)/health/to/help/keep me seeing/support healthy eyesight.
And my heart-because there is so much to do and love
· Help/protect/support/the health of/your bones, brain, eyes and heart
· Stay healthy and active and enjoy life/after menopause/with the product.

Warnings

Do not take while on warfarin therapy without medical advice.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size | **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

colecalciferol	**25 microgram**
concentrated fish Omega-3 triglycerides	**500 mg**
lutein	**6 mg**
Tagetes erecta	**10 mg**
Equivalent: Tagetes erecta (Dry)	500 mg
Trifolium pratense	**100 mg**
Equivalent: Trifolium pratense (Dry)	2.5 g
ubidecarenone	**30 mg**

Public Summary

COMPLAINTS RESOLUTION PANEL DETERMINATION

Complaint 2017-10-005 Promensil products

ARTG IDs: 151247, 154445, 288443

Meeting held 18 January 2018

Complaint summary^

Complainant	Dr Ken Harvey
Advertisers	Pharmacare Laboratories Pty Ltd
	Sigma Healthcare Limited (Amcal)
	Australian Pharmaceutical Industries Ltd (Priceline)
	Chemist Warehouse
Subject matter of complaint	Internet advertisements
Type of determination	Final
Sections of the Code, Regulations or Act found to have been breached*	Act section 22(5)
	Code sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(f), 4(4)
Sections of the Code, Regulations or Act found not to have been breached*	Code sections 6(3)(c), 6(3)(d)
Sanctions	Withdrawal of representations
	Withdrawal of advertisement

* only sections of the Code, Act, or Regulations that were part of the complaint or were raised by the Panel are listed.

The advertisement(s)^

1. The complaint concerned internet advertisements published at the websites *www.promensil.com.au, www.youtube.com, www.amcal.com.au, www.priceline.com.au* and *www.chemistwarehouse.com.au,* viewed by the complainant in October 2017.

2. The advertisement at *www.promensil.com.au* included representations such as "Promensil is a specifically formulated menopause supplement with a natural, standardised isoflavone active ingredient which is well researched, for women wanting natural menopause support." The word "natural" was linked to a footnote stating, "Natural active – standardised extract of Red Clover isoflavones". The word "researched" was linked to footnote stating "studies on Promensil Menopause Double Strength or same standardized 80mg isoflavone red clover extract."

3. This advertisement also included:

   a) under the heading "what makes Promensil Unique", the representations:

      i) "selective seed specifically developed, rich in phyto-estrogen";

      ii) "a specialized extraction process to ensure highest possible phytoestrogen content and quality";

      iii) "clinically trialled dose in Promensil Double Strength";

      iv) "numerous clinical trials during the development phases to ensure the final product was at the right dose tested on the right population groups"; and,

      v) "evidence to support products are well tolerated in healthy women";

   b) under the heading "Why you can trust and rely on Promensil!" and the subheading "Clinical trials on red clover, the ingredient in Promensil Double Strength showed reductions in the frequency of", the representations:

      i) "hot flushes ranging from 5% to 83%";

      ii) "night sweats ranging from 62.3%t to 71.3%";

      iii) "a reduction in overall menopausal symptoms of 68.7%"; and,

      iv) "plus, may relieve mild anxiety."

   c) under the heading "references", a list of 11 references including, for some of the references, a footnote stating "these studies were not conducted with Promensil but with a different product containing red clover extract";

   d) under the heading "Promensil Looking After You During & Beyond Menopause", the representations "estrogen levels decline during and post menopause… Promensil's unique ingredient rich in natural phyto-estrogens continues to aid and support women's health during and post menopause"; and,

   e) under the heading "How long should I take Promensil for?", the representation "You should be able to assess the benefits of taking Promensil after the first 4 weeks. Thereafter, take Promensil daily to maintain benefits."

4. The advertisement at *www.youtube.com* included representations such as "reduce overall menopause symptoms by 68%", "helps reduce hot flushes from 5% to 83%", "helps reduce frequency of night sweats from 62% to 71%", and other claims.

5. The advertisement at *www.amcal.com.au* included the representation "Double Strength may also assist in relieving anxiety", and other claims.

6. The advertisement at *www.priceline.com.au* included the representation "reliefs [sic] the symptoms of menopause such as hot flushes, mood swings, anxiety and night sweats."

7. The advertisement at *www.chemistwarehouse.com.au* included the representations "After menopause" and "Supports: Healthy heart; Healthy bones & teeth; Cognitive health & brain function; Healthy eyes", "helps relieve: moderate menopause symptoms (hot flushes, night sweats and mild anxiety)", and other claims.

8. Excerpts of the advertisements can be viewed in the relevant Appendix to this determination.

The product(s)

9. The advertisements promoted the products Promensil Menopause (AUST L 151247), Promensil Menopause Double Strength (AUST L 154445) and Promensil Women's Health (AUST L 288443).

The advertiser(s)

10. The advertisers were Pharmacare Laboratories Pty Ltd (the sponsor of the products), Sigma Healthcare Limited, Australian Pharmaceutical Industries Ltd and Chemist Warehouse.

The complaint^

11. The complainant was Dr Ken Harvey.

12. It should be noted that the complainant, in setting out his complaint, referred to particular representations without stating expressly which of the advertisements contained each representation. However, it was clear that each of the representations cited by the complainant appeared within one advertisement or another. The effect of this was that the complainant made allegations about each of the advertisements as follows:

    a) The complainant alleged that the advertisement at *www.promensil.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claim "a natural, standardised isoflavone active ingredient which is well researched (studies on Promensil Menopause Double Strength or same standardized 80mg isoflavone red clover extract)." The complainant argued that the words "well researched" implied to the average consumer that "the product is efficacious…. and would encourage inappropriate use";

    b) The complainant alleged that the advertisement at *www.promensil.com.au* breached section 4(4) of the Code because the "same standardized 80mg isoflavone red clover extract" referred to in the advertisements was "not standardised with respect to the various isoflavone constituents and thus are not necessarily comparable."

    c) The complainant alleged that the advertisement at *www.promensil.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(f) and 4(4) of the Code because the references to results such as "clinical trials… on red clover, the ingredient in Promensil Double Strength, showed

reductions in the frequency of: Hot flushes ranging from 5% to 83%; Night sweats ranging from 62.3% to 71.3%; A reduction in overall menopausal symptoms of 68.7%; Plus, may relieve mild anxiety". The complainant argued that these claims "pool[ed] results from different trials; reference 1 & 2 did not use Promensil; reference 3 found no significant difference in the frequency of hot flushes between Promensil and a placebo, and the sponsor has not cited the Cochrane analysis of 5 trials that found no significant difference in the incidence of hot flushes between women taking Promensil or a placebo."

d) The complainant alleged that the advertisements at *www.youtube.com* breached sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(f) and 4(4) of the Code for the same reasons.

e) The complainant alleged that the advertisements at *www.youtube.com* breached sections 6(3)(c) and 6(3)(d) of the Code because mandatory warning statements were "too brief and illegible".

f) The complainant alleged that the advertisement at *www.promensil.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claims "estrogen levels decline during and post menopause. Promensil's unique ingredient, rich in natural phytoestrogens continues to aid and support women's health during and post menopause", for the reasons noted above. The complainant also alleged that the reference to "post menopause" breached section 22(5) of the Act "as "post-menopause" is not an indication contained on the ARTG."

g) The complainant alleged that the advertisement at *www.priceline.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claim "relieves the symptoms of menopause such as hot flushes, mood swings, anxiety and night sweats".

h) The complainant alleged that the advertisement at *www.amcal.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claims "Double Strength may also assist in relieving anxiety".

i) The complainant alleged that the advertisement at *www.chemistwarehouse.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claims "Helps relieve: Moderate menopause symptoms (hot flushes, night sweats and mild anxiety)" and "Supports: Healthy heart; Healthy bones & teeth; Cognitive health & brain function; Healthy eyes".

j) The complainant alleged that the advertisement at *www.promensil.com.au* breached section 4(2)(f) of the Code because of the claim "thereafter, take Promensil daily to maintain benefits".

13. The complainant referred to the research material cited in the advertisements and stated that he had experienced some difficulty in finding one of the studies. He referred to three studies cited in the *www.promensil.com.au* advertisement and stated that a fourth reference, "data on file", was "unacceptable as it cannot be assessed."

14. The complainant also referred to and attached a copy of a 2013 Cochrane Review entitled "Phytoestrogens for menopausal vasomotor symptoms", which the complainant stated had concluded that "no significant difference overall was found in the incidence of hot flushes between women taking Promensil or a placebo."

15. The complainant also referred to and attached a copy of a 2017 systematic review by Myers at al, noting that of the five studies used in this review four had been analysed in the Cochrane Review, the fifth study being a 2012 study by Lipovac et al. The complainant noted that the authors of the Myers review "failed to cite the Cochrane systematic review", and alleged that "the senior author (Stephen Myers, Southern Cross University) has acted as a consultant to Pharmacare Laboratories Pty Ltd on regulatory and research matters and was supported by a grant by Pharmacare Laboratories to undertake this systematic review and meta-analysis."

16. The complainant stated: "The authors believed they had shown statistical and clinically significant benefit for using a specific standardised extract of red clover isoflavones (Promensil) at 80 mg/day for treating hot flushes in menopausal women and there may also be additional benefits that deserve further investigation. However, they did concede that the benefit of using this specific extract at the specified dose warranted independent replication by a group funded from non-commercial sources."

17. The complainant stated that he was "unaware of any good evidence that shows" that the advertised Promensil Women's Health product would support "Healthy Heart, Healthy bones and teeth, Cognitive health & brain function & Healthy eyes, in normal, healthy, menopausal women."

The advertisers' response to the complaint^

18. Sigma Healthcare Limited (Sigma) responded in relation to the alleged breaches arising from the words "Double Strength may also assist in relieving anxiety" by noting "that this wording was provided by the Sponsor and is used in the ARTG Public Summary Document, although Sigma further notes that the ARTG Public Summary document refers to 'mild anxiety', rather than just 'anxiety'", and stated that it would amend the website to include the word "mild", describing its omission as a "typographical error".

19. Sigma responded in relation to the alleged breaches of sections 6(3)(c) and 6(3)(d) of the Code by "acknowledge[ing] that the advertisement lacked the mandatory warnings required under these sections of the Code" and stated that "this was the result of an administrative oversight."

20. Australian Pharmaceutical Industries Ltd (API) responded by stating that it was "not responsible for the claims made on the product, the advertisement video, and ARTG Public Summary, the subject of the [present complaint], or any part of it", and that "Priceline Pty Ltd (a subsidiary of API), markets and sells the particular product only." API stated: "the supplier of the product, Pharmacare Laboratories, provided the product packaging images and content to Priceline for Priceline to display on its website. As Pharmacare own all intellectual property subsisting in the product, including the packaging and content, Priceline can only advertise the images and information approved and provided by Pharmacare."

21. API also noted that the *priceline.com.au* advertisement did not contain most of the claims cited by the complainant.

22. Chemist Warehouse acknowledged receipt of the complaint but did not otherwise respond.

23. Pharmacare Laboratories Pty Ltd (Pharmacare) responded through its lawyers. For simplicity the response provided by the lawyers is described in terms of Pharmacare's response in this determination.

24. Pharmacare argued that the substance of the complaint had already been dealt with in complaint 2015/09/018 and that the present complaint ought therefore to be treated as withdrawn pursuant to regulation 42ZCAF of the Regulations.

25. Pharmacare argued that the words "well researched" were "clearly… a reference to the active ingredient only, not the product as a whole", and listed nine published studies that related to "the use of red clover isoflavones during menopause." Pharmacare stated that of those studies, two involved Promensil and "a number of the studies" involved Menoflavon, which "is owned, marketed and distributed by PharmaCare in selected European countries, formulated to provide support and wellbeing for women during and after menopause." Pharmacare stated that "the Red Clover extract in Menoflavon is the same as that which is used by PharmaCare in Promensil", and provided evidence in support of this statement.

26. Pharmacare referred to the Myers study and stated that it had concluded that "'[t]here is evidence for a statistical and clinically significant benefit for using a specific standardised extract of red clover isoflavones (Promensil) at 80 mg/day for treating hot flushes in menopausal women across the 3 studies included in the meta-analysis" and that it supported a view that there was a statistically significant difference between women receiving red clover and those receiving placebo in relation to menopause symptoms.

27. In relation to the alleged breach of section 4(4) of the Code because the "same standardized 80mg isoflavone red clover extract" referred to in the advertisements was "not standardised with respect to the various isoflavone constituents and thus are not necessarily comparable", Pharmacare argued that "literature relevant to Menoflavon is able to be relied upon for the purposes of Promensil" as these products contained the same active ingredient.

28. Pharmacare also stated that the citation for "reference 1", which the complainant had alleged was incorrectly cited, was in fact correctly cited, and provided a copy of "the relevant article showing the cited reference."

29. In relation to the "quantified claims", Pharmacare referred to three studies and stated that they "substantiate[d] the percentage range claims for hot flushes and night sweats", and stated that it "rejects the proposition that the 'pooling' of results breaches the Code, in relation to the hot flush and night sweat claims, as the representations transparently display the range of expected frequency reduction, and the referenced study to which the specific percentage in that range is attributed."

30. Pharmacare argued that "the Cochrane review on which the complainant relies was conducted prior to the systematic review conducted by Professor Myers" and that "the complainant appears to have selectively cited [the Cochrane] review and appears to have completely ignored the finding that '[s]ome trials reported a slight reduction in hot flushes and night sweats with phytoestrogen-based treatment.'"

31. Pharmacare stated that it had, without admission, removed the *www.youtube.com.au* advertisement.

32. In relation to the words "post menopause", Pharmacare stated that it had amended this reference in the *www.promensil.com.au* advertisement so that it used the words "after menopause."

33. Pharmacare also provided a range of evidence material in relation to the Promensil Women's Health product generally, and the "post menopause" claim made in relation to it, and noted that

the indications on the Register for this product included references to "healthy post menopause" and "for during and after menopause."

34. In relation to the claim about relieving anxiety, Pharmacare provided evidence material and stated that it had advised Priceline to amend its website to refer to mild anxiety.

35. In relation to the daily dosage, Pharmacare stated that it had altered the wording on the *www.promensil.com.au* website to address the alleged breach of section 4(2)(f) of the Code.

36. Pharmacare included in its response a range of evidence material in support of its response. This included published reports of original research, monograph material, and material from a manufacturer supporting a view that the active ingredient in Promensil was the same as the active ingredient in another product, Menoflavin, and other material.

Findings of the Panel

prior decision of Panel

37. Pharmacare argued that the present complaint ought to be treated as withdrawn as its substance had already been dealt with in a prior complaint, 2015/09/018, and the Panel's decision in the prior complaint was currently the subject of review within the TGA.

38. The Panel did not accept this argument. The prior complaint related to an advertisement for only one of the three products advertised in the present complaint. The subject matter of the prior complaint was confined to:

    a) the use of the word "natural";

    b) the absence of the words "always use the label" and "use only as directed";

    c) possible breaches of section 4(2)(i) of the Code because of the words "backed by 15 years of scientific research on effectiveness and safety" and "Promensil has a good safety profile"; and,

    d) possible breaches of section 4(4) of the Code because of the words "Promensil is the most extensively studied menopause supplement. Promensil has been used in international scientific research into effects of red clover supplementation during menopause for over 15 years. Studies have shown that Promensil has a good safety profile and may help to maintain good general health during menopause and offer additional support to the usual vitamin and soya blends, namely: contribute to comfortable menopause ... may help maintain healthy bones ... may help maintain a healthy cardiovascular system by maintaining the elasticity of blood vessels and contributing to normal lipid profile."

39. The Panel noted that the advertisements cited in the present complaint were not the advertisement cited in the prior complaint, and that:

    a) the use of the word "natural" was not in issue in the present complaint;

    b) the absence of mandatory statements such as "always use the label" and "use only as directed" is a matter for consideration in relation to any published advertisement while it is published and must always be considered on a case-by-case basis;

    c) claims about safety were not in issue in the present complaint;

d) the present complaint involved representations about efficacy and research that were, at a minimum, expressed differently and in a different context to those raised in the prior complaint, and in any event different provisions of the Code and Act were alleged to have been breached.

40. In particular, the Panel noted that the prior complaint related in part to the words "most extensively studied menopause supplement", while the present complaint related to words such as "well researched".

41. The Panel was satisfied that the present complaint should not be treated as withdrawn and should be dealt with in its entirety.

responsibility for the advertisements

42. Under regulation 42ZCAA of the Regulations, the person apparently responsible for an advertisement is the person who, based on the particulars of a complaint and the assessment of the Panel, appears to be responsible for requesting the publication of the advertisement.

43. Based on the material before it, the Panel was satisfied that:

a) Pharmacare Laboratories Pty Ltd was responsible for all of the advertisements;

b) Sigma Healthcare Limited was responsible for the advertisement at *www.amcal.com.au*;

c) Australian Pharmaceutical Industries Ltd was responsible for the advertisement at *www.priceline.com.au*; and,

d) Chemist Warehouse was responsible for the advertisement at *www.chemistwarehouse.com.au*.

assessing the claims in the advertisements

44. Section 1(3) of the Code states that the Code should be interpreted with an emphasis on the object and the principles of the Code, and the total presentation and context of the advertisement. Section 3(2) of the Code states that the conformity of an advertisement with this Code should be assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed. In assessing the advertisements, the Panel was mindful not only of the particular words cited by the complainant, but of the entire context of each advertisement and its likely impact on a reasonable consumer.

the evidence material

45. The complainant referred to a range of evidence material, including material cited in the advertisements, together with a Cochrane Review related to hot flushes in menopause. He argued that there was either no evidence or insufficient evidence to support the claims he highlighted in his complaint.

46. Pharmacare provided a range of evidence material in support of its response. This material included published reports on original research, monograph material, and published review material. The evidence in relation to the Promensil and Promensil Double Strength products was distinct from the evidence in relation to the Promensil Women's Health product, as the Women's Health Product contained different ingredients.

47. Pharmacare provided nine published reports on original research in relation to the red clover extract active ingredient. The Panel noted, however, that there appeared to be some duplication between these studies, in that:

    a) Chedraui et al 2006, and Hidalgo 2005 appeared to duplicate the same subject population and the same study site, with the Chedraui paper being a "brief communication" on the effects of red clover extract (MF11RCE) on vaginal cytology, which appeared to be a subset of the reported results of the lengthier Hidalgo paper which reported on menopausal symptoms. In effect, the two papers were two reports arising from a single study;

    b) Lipovac 2011 (two studies) and 2010 all appeared to involve the same study population of 109 women (after four women were excluded); in effect, the three papers were three reports on a single study, that each reported on different outcomes from the same study population. Only one of the Lipovac studies (2011) reported on vasomotor and menopausal symptoms, with the other two studies reporting on skin and mucosal status, and depressive and anxiety symptoms;

    c) Imhof (2006) also appeared to involve the same 109 patients as the Lipovac papers (noted above), reporting on endometrium and sex hormones in this group of postmenopausal women; and

    d) The study of 109 patients (from which the study reports by Lipovac (2010, 2011) and Imhof (2006) were published) was conducted between May 2003 and November 2004, with the four separate studies reporting different study endpoints or outcomes.

48. The total body of evidence was therefore significantly smaller, in terms of the number of subjects involved in clinical trials, than it superficially appeared to be. Moreover, while new statistical analysis might (or might not) have been done for the 2010 and 2011 papers, the clinical trial itself for the Imhof/Lipovac papers involved a clinical intervention conducted in 2003-2004. The total body of evidence was therefore also less recent than it initially appeared to be.

evidence in relation to hot flushes

49. In relation to hot flushes, the most significant evidence before the Panel was the Myers et al 2017 review, and the 2013 Cochrane Review.

50. The Panel noted that the Myers et al 2017 systematic review stated, in its conclusion, that "the benefit of using this specific extract at the specified dose are significant enough to warrant independent replication by a group funded from non-commercial sources." The Panel also noted that this review covered a subset of the material reviewed in the 2013 Cochrane review.

51. The conclusion of the Cochrane review in relation to red clover extracts was that "no evidence suggested that red clover extracts had a positive effect on hot flush frequency or severity". This conclusion took into account inconsistent results between studies, noting for example that "findings were inconclusive and could largely be explained by risk of bias" and that "the two larger studies [involving red clover extracts] at low risk of bias found no evidence of benefit with red clover extracts."

52. Taking into account the conclusions of both the Myers review and the Cochrane review, and considering the individual studies referred to by Pharmacare, the Panel was satisfied that the totality of evidence before it supported a view that:

a) there could be some preliminary or suggestive basis for a view that red clover extracts, including the red clover extract used in the advertised Promensil Menopause and Promensil Menopause Double Strength products, could offer benefits in relation to hot flushes during menopause; but,

b) there was currently no sufficient body of evidence to support claims in advertisements directed to consumers that the advertised Promensil Menopause and Promensil Menopause Double Strength products would have any benefits in relation to hot flushes during menopause.

evidence in relation to night sweats

53. The Panel noted that night sweats, like hot flushes, are vasomotor symptoms of menopause. Both the Myers review and the Cochrane Review referred to night sweats, but at times expressed conclusions in relation to hot flushes without any proximate mention of night sweats. It appeared to the Panel that the best view of the evidence in relation to night sweats was that it was essentially the same as the evidence in relation to hot flushes; that is, that:

    a) there could be some preliminary or suggestive basis for a view that red clover extracts, including the red clover extract used in the advertised Promensil Menopause and Promensil Menopause Double Strength products, could offer benefits in relation to night sweats during menopause; but,

    b) there was currently no sufficient body of evidence to support claims in advertisements directed to consumers that the advertised Promensil Menopause and Promensil Menopause Double Strength products would have any benefits in relation to night sweats during menopause.

evidence in relation to anxiety

54. In relation to anxiety, Pharmacare relied upon two published studies – Lipovac 2010 published in *Maturitas*, and Lipovac 2011 published in *Gynecological Endocrinology*. It is to be noted that these two published reports concerned the same clinical trial.

55. The Panel was satisfied that, although presented as two reports, a single study was not sufficient to support claims in advertisements directed to consumers about anxiety or mild anxiety.

evidence in relation to overall menopausal symptoms

56. Noting its findings in relation to hot flushes, night sweats, and anxiety, the Panel was unable to find any sufficient support in the evidence material for claims in advertisements directed to consumers about overall menopausal symptoms or non-specific references to benefits in relation to menopause or menopause symptoms.

57. The Panel was also satisfied that there was no sufficient support in the evidence material for claims in advertisements directed to consumers about "mood swings".

evidence and the "well researched" claim

58. The words "Promensil is a specifically formulated menopause supplement with a natural, standardised isoflavone active ingredient which is well researched, for women wanting natural menopause support" appeared in the advertisement at *www.promensil.com.au*. Their context at *www.promensil.com.au* included references to "selective seed specifically developed, rich in

phyto-estrogen", "a specialized extraction process to ensure highest possible phytoestrogen content and quality", "clinically trialled dose in Promensil Double Strength", "numerous clinical trials during the development phases to ensure the final product was at the right dose tested on the right population groups", "evidence to support products are well tolerated in healthy women", and "Clinical trials on red clover, the ingredient in Promensil Double Strength showed reductions in the frequency of: hot flushes ranging from 5% to 83%; night sweats ranging from 62.3%t to 71.3%; a reduction in overall menopausal symptoms of 68.7%; plus, may relieve mild anxiety", and a list of references including references to published research results.

59. The Panel was satisfied that an ordinary and reasonable consumer viewing the words "well researched", in their context, would take them to convey that:

    a) the active ingredient in the advertised Promensil Menopause and Promensil Menopause Double Strength products had been the subject of a sufficient body of research to establish with a high level of confidence its effects as a medicine; and,

    b) that this body of research had established that the active ingredient would have the effects described throughout the advertisement, including benefits in relation to menopause, the stated reduction in the frequency of hot flushes, night sweats, and overall menopause symptoms, and mild anxiety.

evidence for claims about the Women's Health product

60. The advertisement at *www.chemistwarehouse.com.au* included claims that the Promensil Women's Health product was for "After menopause" and that it "supports: Healthy heart; Healthy bones & teeth; Cognitive health & brain function; Healthy eyes".

61. The Panel was satisfied that an ordinary and reasonable consumer viewing these claims in their context would conclude that the advertised Promensil Women's Health product offered the stated benefits on some basis that was related to the post-menopausal status of the consumers to whom the advertisement was directed.

62. The evidence Pharmacare provided in relation to this product, included some published results of clinical trials, and a range of monograph or textbook material. Pharmacare's submission on this aspect of the complaint did not include any commentary or explanation as to the dosage of each ingredient in the advertised product and its relevance to the claims made in the advertisement.

63. It was unclear to the Panel that the evidence material provided in relation to this aspect of the complaint could be regarded as relevant at all. For example, the advertiser included as part of its evidence the AREDS 2 study, a well-known study involving a very specific formulation and age-related macular degeneration. The advertised Promensil Women's Health product was not the AREDS 2 formulation, "supports… healthy eyes" is not a claim about age-related macular degeneration, and post-menopausal women are not the same population as the population in the AREDS 2 study, which was selected on the basis that it was at elevated risk for late age-related macular degeneration due to the presence of large drusen (the presence of which is associated with late AMD) in one or both eyes and in some cases late AMD in one eye.

64. In the absence of clear guidance from Pharmacare as to the relevance of the evidence material to the claims about the Promensil Women's Health product, and noting that the evidence appeared on its face to be of limited relevance to either the product or the claims, or both, the Panel was satisfied on the basis of the material before it that there was insufficient evidence to support the

claims that the Promensil Women's Health product "supports: Healthy heart; Healthy bones & teeth; Cognitive health & brain function; Healthy eyes".

provisions alleged to have been breached

65. Section 22(5) of the Act makes it an offence to advertise therapeutic goods for an indication, where the indication is not an indication accepted in relation to the inclusion of the goods in the Register.

66. Section 4(1)(b) of the Code requires that advertisements for therapeutic goods "contain correct and balanced statements only and claims which the sponsor has already verified."

67. Section 4(2)(a) of the Code prohibits representations that are "likely to arouse unwarranted and unrealistic expectations of product effectiveness".

68. Section 4(2)(c) of the Code prohibits representations that "mislead directly or by implication or through emphasis, comparisons, contrasts or omissions".

69. Section 4(2)(f) of the Code prohibits representations that "encourage inappropriate or excessive use" of therapeutic goods.

70. Section 4(4) of the Code requires scientific information to be "presented in a manner that is accurate, balanced and not misleading", and requires that publication of scientific research results should "identify the researcher and financial sponsor of the research."

71. Advertisements for therapeutic goods are also required in certain circumstances to include the words "always read the label" (section 6(3)(c) of the Code), and the words "use only as directed" and "if symptoms persist see your doctor/healthcare professional" (section 6(3)(d) of the Code).

indications not on the Register

72. The complainant alleged that a reference to "post menopause" in the *www.promensil.com.au* advertisement breached section 22(5) of the Act "as "post-menopause" is not an indication contained on the ARTG." The claim appeared under the heading "About Promensil" and did not appear to be confined to any one of the three advertised products.

73. Pharmacare stated that it had amended this reference in the *www.promensil.com.au* advertisement so that it used the words "after menopause."

74. The indications on the Register for the Promensil Menopause product did not include reference to post-menopause. The indications on the Register for the Promensil Menopause Double Strength product included reference to "after menopause". The indications on the Register for the Promensil Women's Health product did include reference to post-menopause.

75. The Panel was satisfied that the claim "continues to aid and support women's health during and post menopause" was unsupported by any indication on the Register for the Promensil Menopause product, but that it was supported by an indication on the Register for both the Promensil Menopause Double Strength product, and the Promensil Women's Health product.

76. The Panel therefore found this aspect of the complaint to be justified in relation to the Promensil Menopause product, but not in relation to the Promensil Menopause Double Strength product or the Promensil Women's Health product.

"well researched"

77. The complainant alleged that the advertisement at *www.promensil.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claim "well researched".

78. For the reasons noted above, the Panel was satisfied that the "well researched" claim had not been verified, was not correct and balanced, was likely to arouse unwarranted expectations, and was misleading, in breach of sections 4(1)(b), 4(2)(a) and 4(2)(c) of the Code.

79. The Panel found, therefore, that these aspects of the complaint were justified.

80. However, the Panel did not find that the "well researched" claim breached section 4(2)(f) of the Code by encouraging inappropriate or excessive consumption of the advertised products.

81. The Panel found, therefore, that this aspect of the complaint was not justified.

comparable extracts

82. The complainant alleged that the advertisement at *www.promensil.com.au* breached section 4(4) of the Code because the "same standardized 80mg isoflavone red clover extract" referred to in the advertisements was "not standardised with respect to the various isoflavone constituents and thus are not necessarily comparable."

83. In response, Pharmacare argued that "literature relevant to Menoflavon is able to be relied upon for the purposes of Promensil."

84. On the basis of the material before it, it appeared to the Panel that there were studies that involved either Promensil or Menoflavon, and that each of these studies would be relevant to both products. While the Panel did not find the body of evidence as a whole satisfactory (see above), the Panel did not find the reference to the "same standardized 80mg isoflavone red clover extract" itself to breach section 4(4) of the Code.

85. The Panel found, therefore, that this aspect of the complaint was not justified.

the quantified claims

86. The complainant alleged that the advertisement at *www.promensil.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(f) and 4(4) of the Code because the references to results such as "clinical trials… on red clover, the ingredient in Promensil Double Strength, showed reductions in the frequency of: Hot flushes ranging from 5% to 83%; Night sweats ranging from 62.3% to 71.3%; A reduction in overall menopausal symptoms of 68.7%; Plus, may relieve mild anxiety."

87. The complainant also alleged that the advertisements at *www.youtube.com* breached sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(f) and 4(4) of the Code for the same reasons.

88. The complainant argued that these claims "pool[ed] results from different trials" and that in any event the listed references neither fully supported the claims nor represented the full body of relevant evidence.

89. As noted above, the Panel was satisfied that the evidence material before it was not capable of supporting the claims about product benefits cited by the complainant.

90. Moreover, the Panel agreed with the complainant that the "pooling" of results from different studies (as when representing research results in a form such as "reductions in the frequency of … hot flushes ranging from 5% to 83%") was misleading as it implied that consumers using the product could expect a reduction of between 5 and 83 percent, when in fact the figures of 5 percent and 83 percent were simply inconsistent study results which ought to prompt further investigation and could not be taken to indicate that this range of results could be expected.

91. The Panel was therefore satisfied that these "quantified" claims had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(4) of the Code.

92. The Panel found, therefore, that these aspects of the complaint were justified.

93. However, the Panel did not find that these claims breached section 4(2)(f) of the Code by encouraging inappropriate or excessive consumption of the advertised products.

94. The Panel found, therefore, that this aspect of the complaint was not justified.

"estrogen levels decline during and post menopause. Promensil's unique ingredient, rich in natural phytoestrogens continues to aid and support women's health during and post menopause"

95. The complainant alleged that the advertisement at *www.promensil.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claims "estrogen levels decline during and post menopause. Promensil's unique ingredient, rich in natural phytoestrogens continues to aid and support women's health during and post menopause".

96. The Panel was satisfied that, because of its findings in relation to evidence noted above, the claim that "Promensil's unique ingredient, rich in natural phytoestrogens continues to aid and support women's health during and post menopause" was not supported by adequate persuasive evidence, the claim had not been verified, was not correct and balanced, was likely to arouse unwarranted expectations, and was misleading, in breach of sections 4(1)(b), 4(2)(a) and 4(2)(c) of the Code.

97. The Panel found, therefore, that these aspects of the complaint were justified.

98. However, the Panel did not find that this claim breached section 4(2)(f) of the Code by encouraging inappropriate or excessive consumption of the advertised products.

99. The Panel found, therefore, that this aspect of the complaint was not justified.

100. The Panel also noted without making any formal finding that the reference to "estrogen levels declin[ing] during and post menopause", coupled with the reference to "natural phytoestrogens [that] continue[] to aid and support women's health during and post menopause" appeared to imply that phytoestrogens in the Promensil products could act as replacements for declining natural estrogen.

"relieves the symptoms of menopause such as hot flushes, mood swings, anxiety and night sweats"

101. The complainant alleged that the advertisement at *www.priceline.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claim "relieves the symptoms of menopause such as hot flushes, mood swings, anxiety and night sweats".

102. The Panel's view of the evidence in relation to these claims was, as noted above, that it was insufficient to support the use of the claims in advertisements directed to consumers.

103. The Panel was therefore satisfied that these claims had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a) and 4(2)(c) of the Code.

104. The Panel found, therefore, that these aspects of the complaint were justified.

105. However, the Panel did not find that these claims breached section 4(2)(f) of the Code by encouraging inappropriate or excessive consumption of the advertised products.

106. The Panel found, therefore, that this aspect of the complaint was not justified.

"Double Strength may also assist in relieving anxiety"

107. The complainant alleged that the advertisement at *www.amcal.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claims "Double Strength may also assist in relieving anxiety".

108. The Panel's view of the evidence in relation to this claim was, as noted above, that it was insufficient to support the use of the claim in advertisements directed to consumers.

109. The Panel was therefore satisfied that the claim had not been verified, was not correct and balanced, was likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a) and 4(2)(c) of the Code.

110. The Panel found, therefore, that these aspects of the complaint were justified.

111. The Panel also found that this claim breached section 4(2)(f) of the Code by encouraging inappropriate or excessive consumption of the advertised products, noting that the advertised products were inappropriate as treatments for anxiety.

112. The Panel found, therefore, that this aspect of the complaint was justified.

"helps relieve: moderate menopause symptoms (hot flushes, night sweats and mild anxiety)" and "supports: Healthy heart; Healthy bones & teeth; Cognitive health & brain function; Healthy eyes"

113. The complainant alleged that the advertisement at *www.chemistwarehouse.com.au* breached sections 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code because of the claims "Helps relieve: Moderate menopause symptoms (hot flushes, night sweats and mild anxiety)" and "Supports: Healthy heart; Healthy bones & teeth; Cognitive health & brain function; Healthy eyes".

114. The Panel's view of the evidence in relation to these claims was, as noted above, that it was insufficient to support the use of the claims in advertisements directed to consumers.

115. The Panel was therefore satisfied that these claims had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a) and 4(2)(c) of the Code.

116. The Panel found, therefore, that these aspects of the complaint were justified.

117. However, the Panel did not find that these claims breached section 4(2)(f) of the Code by encouraging inappropriate or excessive consumption of the advertised products.

118. The Panel found, therefore, that this aspect of the complaint was not justified.

"thereafter take Promensil daily to maintain benefits"

119. The complainant alleged that the advertisement at *www.promensil.com.au* breached section 4(2)(f) of the Code because of the claim "thereafter, take Promensil daily to maintain benefits".

120. The Panel noted that this claim was likely to cause consumers to believe that the advertised products should be taken indefinitely or on a very long term basis. There was no material before the Panel to support a view that the advertised products should be taken indefinitely or on a very long term basis.

121. The Panel therefore found that this claim breached section 4(2)(f) of the Code by encouraging inappropriate or excessive consumption of the advertised products.

122. The Panel found, therefore, that this aspect of the complaint was justified.

mandatory statements

123. The complainant alleged that the advertisements at *www.youtube.com* breached sections 6(3)(c) and 6(3)(d) of the Code because mandatory warning statements were "too brief and illegible".

124. While the Panel found the text for warning statements to be somewhat small, it was shown for a reasonable period of time, and the Panel did not on balance find these aspects of the complaint to be justified.

Sanctions

125. The Panel requests Pharmacare Laboratories Pty Ltd, Sigma Healthcare Limited, Australian Pharmaceutical Industries Ltd and Chemist Warehouse, in accordance with subregulation 42ZCAI(1) of the *Therapeutic Goods Regulations 1990*:

a) to withdraw their respective advertisements from further publication;

b) to withdraw any representations that:

i) the red clover extract ingredient in the advertised Promensil products has been the subject of a sufficient body of research to establish with a high level of confidence its effects as a medicine, and that this body of research had established that the active ingredient would have the effects described throughout the advertisement, including benefits in relation to menopause, the stated reduction in the frequency of hot flushes, night sweats, and overall menopause symptoms, and mild anxiety, including through the use of words such as "well researched";

ii) the Promensil Menopause product is indicated for use after or post menopause;

iii) the red clover extract ingredient in the advertised Promensil products can offer benefits in reducing the frequency of hot flushes, night sweats, or overall menopause symptoms, including reductions at particular specified levels;

iv) the red clover extract ingredient in the advertised Promensil products can offer benefits in relation to anxiety, mild anxiety, or mood swings;

v) the red clover extract ingredient in the advertised Promensil products can aid or support women's health during or after (or "post") menopause;

vi) the Promensil Women's Health product can offer benefits in relation to a healthy heart, bones and teeth, cognitive health, brain function, or the health of the eyes; or,

vii) the advertised products should be taken daily on an indefinite or long-term basis;

c) to give a written undertaking not to use the representations in (b) above in any other advertisement*;

d) where the representation has been provided to other parties such as retailers or website publishers, and where there is a reasonable likelihood that the representation has been published or is intended to be published by such parties, to advise those parties that the representation(s) should be withdrawn; and,

e) within 14 days of being notified of this request, to provide evidence to the Panel of its compliance, including a response in writing that they will comply with the Panel's sanctions, and where appropriate, supporting material such as copies of instructions to advertising agents or publishers, or correspondence with retailers and other third party advertisers.

126. The advertiser's attention is drawn to the provisions of sub-regulations 42ZCAI(3) and (4) which permit the Panel to make recommendations to the Secretary in the event of non-compliance with this request.

Dated 18 May 2018

For the Panel

Allan Asher
Chairman

Appendix A: Definitions and footnotes

In this determination, unless otherwise specified:

a) "the Act" means the Therapeutic Goods Act 1989;

b) "the Regulations" means the Therapeutic Goods Regulations 1990;

c) "the Code" means the Therapeutic Goods Advertising Code;

d) "the Register" means the Australian Register of Therapeutic Goods;

e) "any other advertisement" appearing in sub-regulation 42ZCA1(1)(d) is not confined to advertisements in specified or broadcast media (in relation to which complaints may be made to the Panel under Regulation 42ZCAB). It should be noted that HTML metatags and other information which can be retrieved by internet search engines, whether or not it is ordinarily viewed directly by consumers, constitutes advertisement material.

^Readers of the determination should note that the sections "complaint summary", "the advertisement(s)", "the complaint", and "[a party]'s response to the complaint", are summaries that are intended to aid readers of this document. In reaching its decision, the Panel considered all of the material before it, including material that may not be mentioned specifically in the summaries. The summaries do not form part of the Panel's reasoning.

**Under regulation 42ZCAI of the Regulations, the Panel may request that a representation not be used in any other advertisement unless the advertiser satisfies the Panel that the use of the representation would not result in a contravention of the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations 1990 or the Therapeutic Goods Advertising Code. Under the Panel's procedures, the Panel will not ordinarily give additional consideration to such a matter unless significant new material that was not available at the time of the Panel's determination has become available, or until at least 12 months have passed since the Panel's request was made.*

Appendix B: Excerpts of the Advertisement

What is Promensil?

Promensil is a specifically formulated menopause supplement with a natural^, standardised isoflavone active ingredient which is well researched*, for women wanting natural^ menopause support.

^Natural active- Standardised extract of Red Clover isoflavones

**Studies on Promensil Menopause Double Strength or same standardized 80mg isoflavone red clover extract*

****Always read the label. Use only as directed. If symptoms persist consult your healthcare professional.***

What Makes Promensil Unique

- **Selective seed specifically developed, rich in phyto-estrogen**
- **A specialized extraction process to ensure highest possible phytoestrogen content and quality**
- **Numerous clinical trials during the development phases to ensure the final product was at the right dose tested on the right population groups**
- **Clinically trialled dose in Promensil Double Strength**
- **Evidence to support products are well tolerated in healthy women[1,6,7]**

Why You Can Trust And Rely On Promensil!

Clinical trials[1,2,3] on red clover#, the ingredient in Promensil Double Strength[4], showed reductions in the frequency of:

- **Hot flushes ranging from 5%[5] to 83%[2†]**
- **Night sweats ranging from 62.3%[2†] to 71.3%[1†]**
- **A reduction in overall menopausal symptoms of 68.7%[1†]**
- **Plus, may relieve mild anxiety.**

*REFERENCES

Reference 1. Lipovac M. et al. Gynecological Endocrinology. 2011. 1-5

Reference 2. Hidalgo, L. et al. Gynecological Endocrinology. 2005. 21(5). 257-264

Reference 3. Tice, J.A et al. JAMA. 2003 ; 290 (2):207 – 214

Reference 4. Promensil Double Strength contains 80mg of standardised red clover isoflavones. Data on file.

Reference 5. Imhof, M. et al. Effects of a Red Clover Extract on endomentrium and sex hormones in post menopausal women. Maturitas â€" The European Menopausal Journal 2006 Aug 20;55(1):76-81

Reference 6. Thorup A.C. et al. Evidence-Based Complementary and Alternative Medicine. 2015. 1- 11

Reference 7. Chedraui P. et al. International Journal of Gynecology and Obstetrics. 2006. (95): 296-297

Reference 8. Van de Weijer P. & Barentsen R. The European Menopause Journal. 2002. 187-193.

Reference 9. Lipovac M. et al. 2010. 258-261

Reference 10. Lipovac M. et al. 2011. 1-6.

Reference 11. Clifton-Bligh P.B. et al. 2001. 8 (4): 259-265

Results from various clinical trials on red clover show individual responses may vary. Many women may notice a difference in symptoms within 3 to 8 weeks of daily usage.

†These studies were not conducted with Promensil, but with a different product containing red clover extract.