

# Complaint to TGA – Harmony Menopause Max

## ACKNOWLEDGMENT:

This complaint was worked up by a Monash Honours research student, then checked and submitted by Assoc Prof. Ken Harvey.

## COMPLAINT SUMMARY:

This is an illustrative complaint of a general problem. Other Harmony products that make traditional claims for the relief of menopausal symptoms have similar problems, as do many others. We note the TGA has an ongoing review of listed medicines with traditional indications. This requires a published outcome.

We allege that advertisements for Harmony Menopause Max breach s.42DM,42DL(2) & 22(5) of the Therapeutic Goods Act 1889 and s.9(a),(b),(d), 12(3)(f) & 15(2)(a),(3)(a) of the Therapeutic Goods Advertising Code (No.2) 2018.

Traditional claims that herbal products are efficacious in relieving menopausal symptoms are **NOT** in accord with current scientific evidence or medical opinion. To assist informed consumer choice, at the very least, these products require an educational statement on their labels and promotion, “These claims are based on traditional beliefs and practices, not modern scientific evidence”.

## PRODUCT INFORMATION:

Product name: Harmony Menopause Max  
Company: Harmony Natural Women’s Health  
Sponsor: Martin & Pleasance Pty Ltd  
Address: PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia  
ARTG no: 226918

### Product Ingredients

- Bupleurum falcatum 75 mg Equivalent: Bupleurum falcatum 1.5 g (**Bei Chai Hu**)
- Paeonia lactiflora 214.29 mg Equivalent: Paeonia lactiflora 3 g (**Bai Shao**)
- Rehmannia glutinosa 416.67 mg Equivalent: Rehmannia glutinosa 5 g (**Shu Di Huang**)
- Vitex agnus-castus 20 mg Equivalent: Vitex agnus-castus 200 mg (Chaste tree)
- Colecalciferol .005 mg (Vitamin D)

### Permitted Indications:

- Traditionally used in Chinese medicine to clear/disperse/expel/dissipate/cool blood-heat
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Chinese medicine to decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve night sweats associated with menopause
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of menopause

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- Traditionally used in Chinese medicine to decrease/reduce/relieve hot flushes associated with menopause
- Traditionally used in Chinese medicine to decrease/reduce/relieve aggression/irritability associated with menopause
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Maintain/support (state vitamin/mineral/nutrient) levels in the body

### COMPLAINT DETAILS:

Advertisement	Website	Date Accessed
“Harmony Menopause Max” – Harmony Natural Women’s Health	<ul style="list-style-type: none"> <li>• <a href="https://takeharmony.com.au/harmony-menopause-max/">https://takeharmony.com.au/harmony-menopause-max/</a></li> <li>• <a href="https://www.martinandpleasance.com/product/harmony-max-45-tabs/?v=6cc98ba2045f">https://www.martinandpleasance.com/product/harmony-max-45-tabs/?v=6cc98ba2045f</a></li> </ul>	14/10/2020
“Harmony Menopause Max 45 Tablets” – pharmacy outlets	<ul style="list-style-type: none"> <li>• <a href="https://www.chemistwarehouse.com.au/buy/86351/harmony-menopause-max-45-tablets">https://www.chemistwarehouse.com.au/buy/86351/harmony-menopause-max-45-tablets</a></li> <li>• <a href="https://www.superpharmacy.com.au/products/mp-harmony-max-45-tablets">https://www.superpharmacy.com.au/products/mp-harmony-max-45-tablets</a></li> <li>• <a href="https://healthyessentialsaustralia.com.au/products/martin-pleasance-harmony-menopause-60tabs">https://healthyessentialsaustralia.com.au/products/martin-pleasance-harmony-menopause-60tabs</a></li> <li>• <a href="https://www.goodpricepharmacy.com.au/harmony-menopause-max-45-tablets">https://www.goodpricepharmacy.com.au/harmony-menopause-max-45-tablets</a></li> <li>• <a href="https://discountchemist.com.au/product/harmony-menopause-max-45-tablets/">https://discountchemist.com.au/product/harmony-menopause-max-45-tablets/</a></li> <li>• <a href="https://www.choicepharmacy.com.au/shop/vitamins/womens-health/harmony-menopause-max-45-tablets/">https://www.choicepharmacy.com.au/shop/vitamins/womens-health/harmony-menopause-max-45-tablets/</a></li> <li>• <a href="https://www.mychemist.com.au/buy/86351/harmony-menopause-max-45-tablets">https://www.mychemist.com.au/buy/86351/harmony-menopause-max-45-tablets</a></li> <li>• <a href="https://www.mynaturalhealth.com.au/products/view/harmony-menopause-max">https://www.mynaturalhealth.com.au/products/view/harmony-menopause-max</a></li> <li>• <a href="https://www.wizardpharmacy.com.au/menopause/zen-harmony-menopause-max-tablets-45">https://www.wizardpharmacy.com.au/menopause/zen-harmony-menopause-max-tablets-45</a></li> <li>• <a href="https://www.davidjonespharmacy.com.au/harmony-menopause-max-45-tablets">https://www.davidjonespharmacy.com.au/harmony-menopause-max-45-tablets</a></li> <li>• <a href="https://healthnutsaustralia.com.au/products/martin-pleasance-harmony-menopause-max-60-tablets">https://healthnutsaustralia.com.au/products/martin-pleasance-harmony-menopause-max-60-tablets</a></li> <li>• <a href="https://www.beautyheaven.com.au/body-health/supplements-vitamins/product/menopause-max">https://www.beautyheaven.com.au/body-health/supplements-vitamins/product/menopause-max</a></li> <li>• <a href="https://mosesandco.com.au/harmony-menopause-max-45-tablets/">https://mosesandco.com.au/harmony-menopause-max-45-tablets/</a></li> </ul>	14/10/2020

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	<ul style="list-style-type: none"> <li>• <a href="https://www.pharmacy4less.com.au/harmony-menopause-max-45-tablets.html">https://www.pharmacy4less.com.au/harmony-menopause-max-45-tablets.html</a></li> <li>• Etc.</li> </ul>	
<b>Disputed Claims (screen shots in Appendix):</b>		
Harmony Menopause Website (Appendix A)	<ul style="list-style-type: none"> <li>• “This <u>high potency</u> herbal medicine contains herbs <u>traditionally used in Chinese and Western herbal medicine</u> to relieve symptoms associated with menopause, such as hot flushes, night sweats, sleeplessness and fatigue”</li> <li>• “relieve <u>intense</u> symptoms of menopause”</li> <li>• “relieve <u>intense</u> hot flushes and night sweats”</li> <li>• “Rehmannia helps to relieve hot flushes and night sweats as it <u>clears heat and cools the blood</u>”, “TCM <u>adrenal tonic</u> to improve wellbeing”</li> <li>• “Bupleurum helps relieve irritability and emotional distress”, “<u>assist with Liver Qi (energy)</u>”</li> <li>• “Chaste tree “is <u>clinically trialled and shown to relieve symptoms of PMS</u> such as breast fullness (tenderness), irritability, fluid retention and headaches. “Assists in <u>hormone regulating – balancing</u>”, acts as a “<u>hormone stabiliser</u>”</li> <li>• “Indicated in TCM for sleep problems”</li> <li>• “Peony (<u>nourishes the liver blood &amp; softens the liver</u>) may also be used to stop both night and spontaneous sweating by <u>nourishing the ying level and preserving yin</u>” “assists in <u>hormone regulation and balancing</u>”.</li> </ul>	
Chemist Warehouse (Appendix B)	<ul style="list-style-type: none"> <li>• “Harmony Menopause Max contains <u>higher doses</u> (than original Harmony Menopause) of <u>3 key herbs</u>. This synergistic formula is designed for menopausal women experiencing <b>stronger symptoms</b> of menopause. The potent blend of herbs is traditionally used to support menopausal women and may help relieve <b>strong symptoms</b> of: <ul style="list-style-type: none"> <li>○ Hot flushes</li> <li>○ Night sweats</li> <li>○ Irritability</li> <li>○ Sleeplessness”</li> </ul> </li> </ul>	

### CONCERNS

**First**, the permitted indications selected by Martin & Pleasance for this product on their public summary document (appended) are incomplete; they do not cover the ingredient, “Vitex agnus-castus”, which has a tradition of use in Western herbal medicine, not Chinese traditional medicine.

**Second**, with the exception of Vitamin D, the ARTG permitted indications for this product state, “Traditionally used in Chinese medicine”. Yet, with the exception of, “Bupleurum is a traditional herb used in Chinese medicine”, this important information is **NOT** present on the home webpage page of the Martin & Pleasance advertisement.<sup>1</sup>

<sup>1</sup> <https://takeharmony.com.au/harmony-menopause-max/>

## Complaint to TGA – Harmony Menopause Max

Martin & Pleasance’s ‘add to cart’ web page does state, “contains herbs traditionally used in Chinese and **Western** herbal medicine” but the latter is **NOT** in accord with the ARTG permitted indications.<sup>2</sup>

The TCM claims, “clears heat and cools the blood”, “nourishes the liver blood“, “nourishing the [liver] ying level and preserving yin”, “assist with Liver Qi (energy)” require the label statement, “Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you”.<sup>3</sup>

The claim, “softens the liver”, “hormone regulating – balancing -stabiliser” and “adrenal tonic” are not permissible indications.

The claim, “Chaste Tree is clinically trialled and shown to relieve symptoms of PMS such as breast fullness (tenderness), irritability, fluid retention and headaches”, is **meaningless** as herbal products need quality control and extract standardisation to ensure that clinical trial results can be replicated. In addition, the clinical trials referred to are not cited. We are aware of two small Iranian clinical trial in this area, but details of extract preparation and standardisation were lacking.<sup>4,5</sup>

The Chemist Warehouse website refers to, “potent blend of herbs” ... “traditionally used” but does **NOT** state the tradition referred to.

**Third**, while a search of literature found a number of Traditional Chinese Formulas used for various menopausal symptoms, these differed in ingredient combinations, ratios, and dosages from the Martin & Pleasance product.<sup>6,7,8,9</sup> It appears that the Martin & Pleasance product formulation is arbitrary and not in accord with the tradition of Chinese medicines.

Also, we could not find any evidence from the literature that higher doses (than original Harmony Menopause) of the three key herbs provided better relief for menopausal women experiencing stronger symptoms.

**Given the above, we allege that advertisements for Harmony Menopause Max breach s.42DM,42DL(2) & 22(5) of the Therapeutic Goods Act 1889 and s.9(a),(b),(d) , 12(3)(f) & 15(2)(a),(3)(a) of the Therapeutic Goods Advertising Code (No.2) 2018.**

**Fourth**, a 2015 study titled, “Use of complementary and alternative medicines for menopausal symptoms in Australian women aged 40–65 year” noted that a significant number of women at midlife were using complementary and alternative medicines that are known to be ineffective for managing menopausal symptoms.<sup>10</sup>

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<sup>2</sup> <https://www.martinandpleasance.com/product/harmony-max-45-tabs/?v=6cc98ba2045f>

<sup>3</sup> <https://www.legislation.gov.au/Details/F2019L00262>

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6887765/>

<sup>5</sup> <https://www.journaljammr.com/index.php/JAMMR/article/view/15541/28761>

<sup>6</sup> <https://www.mja.com.au/journal/2001/174/2/effects-chinese-medicinal-herbs-postmenopausal-vasomotor-symptoms-australian>

<sup>7</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3551256/>

<sup>8</sup> <https://pubmed.ncbi.nlm.nih.gov/22990757/>

<sup>9</sup> <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0222383>

<sup>10</sup> <https://www.mja.com.au/journal/2015/203/3/use-complementary-and-alternative-medicines-menopausal-symptoms-australian-women>

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A 2016 Cochrane review titled, “Chinese herbal medicine for menopausal symptoms” concluded, “We found insufficient evidence that Chinese herbal medicines were any more or less effective than placebo or hormone therapy for the relief of vasomotor symptoms. Effects on safety were inconclusive”.<sup>11</sup>

Current medical advice is consistent. The Royal Women’s Hospital, Melbourne states, “There is no evidence for efficacy of herbal supplements”.<sup>12</sup> The Australian Menopause Society says, “There is currently insufficient evidence to support the use of herbal therapies”.<sup>13</sup> The latter body also says, “For the majority of symptomatic menopausal women, tailored hormone therapy has benefits that outweigh the risks”.<sup>14</sup>

**In short, traditional claims that herbal products are efficacious in relieving menopausal symptoms are NOT in accord with current scientific evidence or medical opinion. To assist informed consumer choice, these products require an educational statement on their labels and promotion, “These claims are based on traditional beliefs and practices, not modern scientific evidence”.**

Finally, this is an illustrative complaint of a general problem. Other Harmony Menopause products (and many others) making traditional claims have similar problems. We note the TGA Review of listed medicines with traditional indications. .<sup>15</sup> This requires a published outcome.

SIGNED AND DATED

Dr Ken Harvey MB BS, FRCPA, AM  
Associate Professor  
Department of Epidemiology and Preventive Medicine  
School of Public Health and Preventive Medicine

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Monash University  
Alfred Campus  
553 St Kilda Rd  
Melbourne VIC 3004  
Mobile: +61 419181910  
Email: [kenneth.harvey@monash.edu](mailto:kenneth.harvey@monash.edu)  
WWW: [www.medreach.com.au](http://www.medreach.com.au)

14 October 2020

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<sup>11</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4951187/>

<sup>12</sup> <https://www.thewomens.org.au/health-information/menopause-information/managing-menopause>

<sup>13</sup> [https://www.menopause.org.au/images/stories/infosheets/docs/AMS\\_Complementary\\_and\\_Herbal\\_Medicines\\_Hot\\_Flushes.pdf](https://www.menopause.org.au/images/stories/infosheets/docs/AMS_Complementary_and_Herbal_Medicines_Hot_Flushes.pdf)

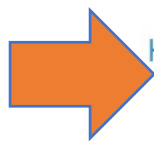
<sup>14</sup> [https://www.menopause.org.au/images/stories/infosheets/docs/AMS\\_Risks\\_and\\_Benefits\\_of\\_MHTHRT.pdf](https://www.menopause.org.au/images/stories/infosheets/docs/AMS_Risks_and_Benefits_of_MHTHRT.pdf)

<sup>15</sup> <https://www.tga.gov.au/review-listed-medicines-traditional-indications>

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## APPENDIX:

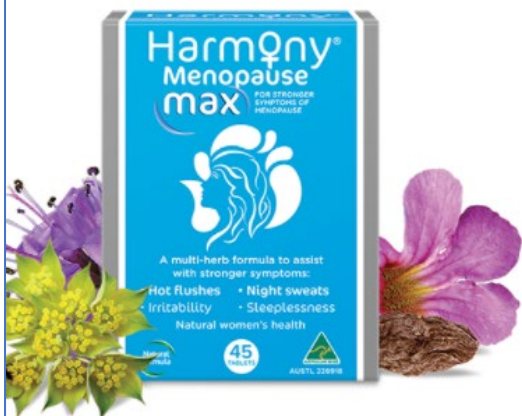
### Harmony Menopause Max



Harmony Menopause Max is a high potency herbal medicine to help relieve intense symptoms of menopause, specifically intense hot flushes and night sweats.



**For when menopause symptoms are at their MAX**



- Multi-herb formula
- For stronger symptoms of menopause
- Relieve intense hot flushes & night sweats
- Potent blend of 4 herbs plus vitamin D3


Always read the label. Follow the directions for use. If symptoms persist, talk to your healthcare professional.

45 Tablets | \$35.60

<https://takeharmony.com.au/harmony-menopause-max/>



## Complaint to TGA – Harmony Menopause Max



**Rehmannia**

Rehmannia is used to help relieve menopausal symptoms as it clears heat and cools the blood to help relieve irritability, restlessness and feverish sensations at night (hot sweats).

[LEARN MORE ABOUT REHMANNIA →](#)

**Chaste Tree**

Chaste Tree may be used for menstrual irregularities and relief of PMS symptoms such as breast tenderness, headaches, irritability and fluid retention. Also used to relieve menopausal symptoms.

[LEARN MORE ABOUT CHASTE TREE →](#)

**Peony**

Peony is used to help relieve complications of women's health. It nourishes the liver blood & softens the liver to help regulate menstruation and alleviate pain. Peony may be used to relieve sweating.

[LEARN MORE ABOUT PEONY →](#)

**Bupleurum**

Bupleurum is a traditional herb used in Chinese medicine to help relieve irritability and emotional distress.

[LEARN MORE ABOUT BUPLEURUM →](#)

**Vitamin D**

Vitamin D helps in regulating calcium and phosphorus levels in the body, and also the development and maintenance of bones, healthy skin and muscle strength.

<https://takeharmony.com.au/harmony-menopause-max/>

# Complaint to TGA – Harmony Menopause Max

## Rehmannia



### Main benefits

- Traditionally used in Chinese medicine to relieve hot flushes and night sweats
- Regulates temperature and clears heat from the blood
- TCM adrenal tonic to improve wellbeing

### Overview

Rehmannia glutinosa (Chinese Foxglove) is a perennial plant of the Phymaceae family, its leaves are at ground level and blooms with flowers that can range from yellow to burgundy in colour.

### How it works

Rehmannia is used to help relieve menopausal symptoms as it clears heat and cools the blood to help relieve irritability, restlessness and feverish sensations at night (hot sweats).

<https://takeharmony.com.au/u-dream/rehmannia/>



## Complaint to TGA – Harmony Menopause Max

### Chaste Tree



#### Main benefits

- Chaste Tree is clinically trialled and shown to relieve symptoms of PMS such as breast fullness (tenderness), irritability, fluid retention and headaches.
- Also used to relieve menopausal symptoms.
- Assists in hormone regulating - balancing.

#### Overview

Chaste Tree (*Vitex Agnus-Cactus*) is a deciduous shrub native to European, Mediterranean and Central Asian countries. It has slender finger-like leaves, purple-black berries and belongs to the Verbenaceae family.

#### How it works

Chaste Tree is a Western herb that has been used since ancient times for gynecological issues such as symptoms of PMS and menopause.

<https://takeharmony.com.au/u-dream/chaste-tree/>

## Complaint to TGA – Harmony Menopause Max



### Main benefits

- Peony is used to relieve complications of women's health and assists in hormone regulation and balancing.
- Indicated in TCM for sleep problems.
- Relieves menstrual (period) pain and cramps.

### Overview

Peony (*Paeonia Lactiflora*) is chiefly produced in the Zhejiang, Anhui and Sichuan provinces.

### How it works

Peony is used to help relieve complications of women's health. It nourishes the liver blood and softens the liver to help regulate menstruation and alleviate pain. Peony may also be used to stop both night and spontaneous sweating by nourishing the ying level and preserving yin.

<https://takeharmony.com.au/u-dream/peony/>

# Complaint to TGA – Harmony Menopause Max

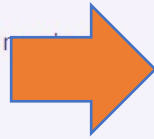


## Main benefits

- Bupleurum is responsible for a smooth flow of energy throughout the body to reduce stress and smooth our emotions.
- It has calming properties to ease anger, irritability and frustration.

## Overview

Bupleurum (Bupleurum Falcatum Root) is a member of the Apiaceae family of plants.



## How it works

Bupleurum is used in Traditional Chinese Medicine (TWM) to assist with Liver Qi (energy) throughout the body.

<https://takeharmony.com.au/u-dream/bupleurum/>

# Complaint to TGA – Harmony Menopause Max



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FREE SHIPPING OVER ~~\$99\*~~ \$50\*  | AUSTRALIA'S #1 ONLINE PHARMACY 

Home / Health / Natural Hormone Replacement



**Harmony Menopause Max 45 Tablets**

Product ID: 2676886

★★★★☆ 4.4 (54) Write a review

**\$26.99**

**\$10.86 Off RRP**

Don't Pay RRP: \$37.85

QTY:   **ADD TO CART**

 **Click & Collect** ⓘ  
[Search For A Pickup Store](#)  
[CLICK HERE](#) ✓

### General Information

When menopause symptoms are at their MAX.

Harmony Menopause **MAX** is the leading double strength Menopause product in the category\*.

Harmony Menopause Max contains higher doses (than original Harmony Menopause) of 3 key herbs. This synergistic formula is designed for menopausal women experiencing **stronger symptoms** of menopause. The potent blend of herbs is traditionally used to support menopausal women and may help relieve **strong symptoms** of:

- Hot flushes
- Night sweats
- Irritability
- Sleeplessness

<https://www.chemistwarehouse.com.au/buy/86351/harmony-menopause-max-45-tablets>