

Complaint to TGA: Martin & Pleasance Pty Ltd, Rescue Sleep Spray & Drops

Acknowledgements:

This complaint was worked up by 2019 Monash BMS3052 students; then checked and submitted by Assoc Prof Ken Harvey.

Product and Sponsor

Product name: Rescue Sleep Spray & Drops

Sponsor: Martin & Pleasance Pty Ltd

Address: 7 Rocklea Drive Port Melbourne VIC 3207

Postal Address: PO Box 2007, South Melbourne, VIC 3205 Australia

ARTG: 153231

Permitted Indications:

- Traditionally used in Bach flower remedies to calm the mind
- Traditionally used in Bach flower remedies to soothe/calm nerves
- Traditionally used in Bach flower remedies to decrease/reduce/relieve symptoms of stress
- Traditionally used in Bach flower remedies to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Bach flower remedies to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Bach flower remedies to maintain/support mental concentration/focus/clarity
- Traditionally used in Bach flower remedies to decrease/reduce/relieve mental overactivity
- Traditionally used in Bach flower remedies to decrease/reduce/relieve sleeplessness

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild anxiety.

Warnings

- Contains ethanol. (or words to that effect).

Active Ingredients

- Aesculus hippocastanum 238 microlitre/mL Equivalent: Aesculus hippocastanum (Fresh) 23.8 microgram/mL
- Clematis vitalba 200 microlitre/mL Equivalent: Clematis vitalba (Fresh) 20 microgram/mL
- Helianthemum nummularium 200 microlitre/mL Equivalent: Helianthemum nummularium (Fresh) 20 microgram/mL
- Impatiens glandulifera 200 microlitre/mL Equivalent: Impatiens glandulifera (Fresh) 20 microgram/mL
- Ornithogalum umbellatum 200 microlitre/mL Equivalent: Ornithogalum umbellatum (Fresh) 20 microgram/mL
- Prunus cerasifera 200 microlitre/mL Equivalent: Prunus cerasifera (Fresh) 20 microgram/mL

Advertisement type:

Internet – Website

Accessed on:

06/01/20

Complaint to TGA: Martin & Pleasance Pty Ltd, Rescue Sleep Spray & Drops

URL(s) listed (screen shots appended)

- http://store.martinandpleasance.com/epages/martinandpleasance.sf/en_AU/?ObjectPath=/Shops/martinandpleasance/Products/MPBHSLEEP20ML
- <https://www.martinandpleasance.com/products/rescue-sleep-20ml-spray/>
- <https://www.rescueremedy.com/en-au/rescue-range/rescue-sleep/rescue-sleep-spray>
- <https://www.chemistwarehouse.com.au/buy/53489/rescue-remedy-sleep-20ml-spray>
- <https://www.priceline.com.au/rescue-rescue-sleep-10-ml>
- https://www.amazon.com.au/Rescue-Sleep-Spray/dp/B00NLA4GF6/ref=sr_1_4?keywords=rescue+sleep&qid=1578455502&sr=8-4
- <https://www.goodpricepharmacy.com.au/bach-rescue-remedy-sleep-drops-10ml>
- <https://www.pharmacy4less.com.au/rescue-sleep-spray-20ml-4.html?amp=1>
- <https://www.yourdiscountchemist.com.au/rescue-remedy-sleep-drops-10ml.html>
- <https://shop.coles.com.au/a/a-national/product/bach-rescue-remedy-sleep-spray>
- <https://www.catch.com.au/product/rescue-sleep-20ml-spray-1992763/?sid=rescue%20sleep&sp=2&st=32&srtrv=sj-88w2qv0u6p8p3mppughpgp.click>
- <https://www.ebay.com.au/itm/Bach-Flower-Remedies-Rescue-Sleep-Spray-20ml-Buy-more-and-Save/323791127109?hash=item4b63748245:g:bywAAOSwhh9cxSmS&frcectupt=true>
- <https://www.woolworths.com.au/shop/productdetails/769741/rescue-remedy-sleep-liquid-spray>
- <https://mojohealth.com.au/products/martinpleasancerescueremedysleep10ml>
- Etc.

Complaint Summary

All web sites cited:

- Fail to point out that this traditional use is not supported by scientific evidence' (s.9(b) Code breach)

Sponsor's web site:

- Contains indications/claims that are not on the ARTG (s.9(d), 10(a)(ii) Code breach)
- Lacks required information for goods not available for physical examination before purchase (s.12(3)(e)&(f) Code breach)
- Lacks the required label statement: If symptoms persist, talk to your health professional (s.13(7) Code breach)
- Lacks the tradition of use in the permitted indication: Traditionally used in Bach flower remedies (s.23 Code breach)

Pharmacy web sites:

- Contains indications/claims that are not on the ARTG (s.9(d), 10(a)(ii) Code breach)
- Lacks required information for goods not available for physical examination before purchase (s.12(3)(e) Code breach)
- Lacks the tradition of use in the permitted indication: Traditionally used in Bach flower remedies (s.23 Code breach).

Introduction

Sleeplessness (insomnia) is commonly experienced, and it is important that complementary medicines claiming to alleviate these symptoms are evidence-based. Regrettably, this is not the case for Rescue Sleep Drops and Sprays.¹

¹ <https://theconversation.com/science-or-snake-oil-do-rescue-remedies-ease-stress-89146>

Complaint to TGA: Martin & Pleasance Pty Ltd, Rescue Sleep Spray & Drops

Disputed claims (screen shots appended):

The traditional claims made for Bach Rescue Remedies such as, **‘relieve sleeplessness, feelings of mild anxiety, nervous tension, stress and provide a sense of focus and calm’** are not supported by scientific evidence (see Appendix I).

The TGA evidence guidelines (pg. 22) state:²

“If you are aware that there is conflicting evidence between the history of traditional use and contemporary scientific evidence for your medicine, then it is advisable to include a statement to this effect in any labelling and advertising associated with the medicine, for example: ‘this traditional use is not supported by scientific evidence’. This will ensure that the advertised information relating to your medicine is truthful, valid and not misleading”.

It is alleged that failure of advertisers to point out that, ‘this traditional use is not supported by scientific evidence’ is a s.9(b) Code breach.

Other Code breaches

Sponsor's web site:

- Contains indications/claims that are not on the ARTG such as ‘restless mind, terror, panic, inattentiveness, irritation, impatience, shock’, ‘switch off the mind from unwanted repetitive thoughts’, ‘Whatever the thoughts preventing you from switching off at night time might be, now that there is RESCUE® Sleep, you can look forward to waking up refreshed and energised in the morning and more importantly, be ready to face the day ahead!’, ‘Helps a restful night’s sleep in times of stress and anxiety’, ‘vegan friendly’, ‘alcohol free’ ‘non habit forming’ and non-drowsy’ (s.9(d), 10(a)(ii) Code breach)
- Lacks required information for goods not available for physical examination before purchase (s.12(3)(e)&(f) Code breach)
- Lacks the required label statement: ‘If symptoms persist, talk to your health professional’ (s.13(7) Code breach)
- Lacks the tradition of use in the permitted indication: Traditionally used in Bach flower remedies (s.23 Code breach)

Pharmacy sites:

- Contains indications/claims that are not on the ARTG such as ‘agitation or despair’, ‘restless mind, frozen terror, panic, inattentiveness, irrational thoughts, irritability, tension, fidgety, impatience, shock, trauma’, ‘for the tendency to pass out and unconsciousness’, ‘fear of mind giving away’, ‘verge of breakdown’, ‘switch off the mind from unwanted repetitive thoughts’, ‘sleeplessness associated with recurring and worrying thoughts’, ‘homeopathic’, ‘gluten free’, ‘free from artificial additives’ and ‘Suitable for vegans’ (s.9(d), 10(a)(ii) Code breach)
- Claims, ‘Safe for the whole family’ (s.10(d)(i) Code breach)
- Lacks required information for goods not available for physical examination before purchase (s.12(3)(e)&(f) Code breach)
- Lacks the tradition of use in the permitted indication: Traditionally used in Bach flower remedies (s.23 Code breach).
- Dose craziness and contradictions, e.g. '2 sprays or 4 drops directly onto the tongue or into a glass of water (sipped at intervals). Rescue Remedy can be taken as often as required and as frequently as every 10 minutes' CW. '4 Sprays directly onto the tongue or into a glass of water (sipped at intervals)' Coles.

² <https://www.tga.gov.au/sites/default/files/evidence-guidelines.pdf>

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Signed and dated

Dr Ken Harvey MB BS, FRCPA, AM
Associate Professor
Public Health and Preventive Medicine
Monash University
9 January 2020

Appendix I

Ernst (2014) conducted a systematic review of controlled clinical trials of flower remedies in humans for any medical condition.

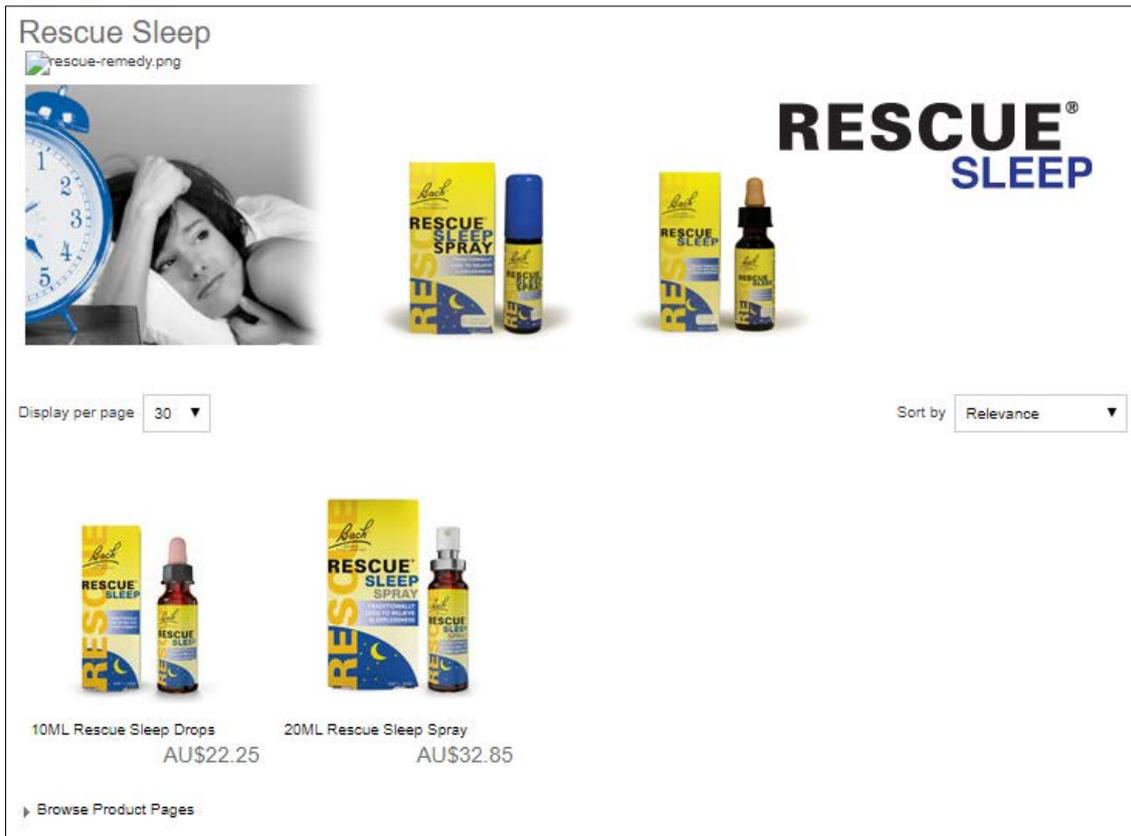
Reference	Study design	Jadad score	Validity score	Sample	Interventions	Main outcome measures	Main result	Comment
von Rühle (1995) [17]	RCT, 3 parallel groups (not placebo controlled, not double-blinded)	2	3	24 pregnant women with overdue births	Individualised flower remedies daily up to date of birth, attention control group (no flower remedies), no such therapies, (all groups had standard care in addition)	Time to birth, type of birth, use of medication during birth, anxiety during birth, well-being	Significantly less medication was used in group A (p = 0.032)	Birth was delayed in group A by 5.1 days, in groups B by 6.6 and in group C by 4.4 days
Armstrong (1999) [18]	RCT, double-blind, 2 parallel arms	5	3	100 healthy University students sitting exams	'Rescue Remedy' (1-4 doses during 7 days before and during exams) placebo (same treatment schedule)	Anxiety measured with Spielberger State-Trait-Anxiety Inventory (SSTAI)	No significant differences between groups	Study suffered from high drop-out rate
Walach (2001) [19]	RCT, double-blind, cross-over	5	3	51 healthy students sitting exams	Rescue Remedy (4 drops daily for 2 weeks or more if necessary) placebo (same treatment schedule)	Anxiety measured with Text-Anxiety Inventory	No significant differences between groups	Primary authors conclude that flower remedies are "an effective placebo"
Pintov (2005) [20]	RCT, double-blind, 2 parallel arms	4	3	40 school children with ADHD	A) Rescue Remedy (4 drops 4x per day for 3 months) B) placebo (same treatment schedule)	Performance evaluated by teacher (Conner's questionnaire)	No significant differences between groups	17 drop outs
Toyota (2006) [21]	RCT, double-blind, 2 parallel groups	3	3	40 surgical patients	A) Rescue Remedy in drinking water B) drinking water without Rescue Remedy	Anxiety and tension (VAS)	No significant differences between groups	Write-up is unclear in several aspects
Halberstein (2007) [22]	RCT, double-blind, 2 parallel groups	2	3	111 students under stressful exam situation	A) Rescue Remedy (5 doses during a 3 hour class) B) placebo	Anxiety measured with SSTAI	No significant differences between groups	A subanalysis of high anxiety students favoured A over B
Forshaw (2009) [23]	RCT, single-blind, 3 parallel groups	4	3	62 students under experimental stress	Rescue Remedy (4 drops in water) Placebo (pure water + participants were told that it contained Rescue Remedy) Placebo (pure water + participants were told that it was water)	Stress (VAS)	No significant differences between groups	All groups reported stress reduction regardless of treatment

Those studies that controlled for placebo-effects and minimised selection bias through randomisation failed to demonstrate effects beyond a placebo response. It was concluded that the hypothesis that flower remedies are associated with effects beyond a placebo response was not supported by data from rigorous clinical trials.³

³ <https://pubmed.ncbi.nlm.nih.gov/12635462-flower-remedies-a-systematic-review-of-the-clinical-evidence/>

Complaint to TGA: Martin & Pleasance Pty Ltd, Rescue Sleep Spray & Drops

Appendix II (Screen shots with offending claims arrowed)



http://store.martinandpleasance.com/epages/martinandpleasance.sf/en_AU/?ObjectPath=/Shops/martinandpleasance/Categories/Rescue_Remedy/Rescue_Sleep



http://store.martinandpleasance.com/epages/martinandpleasance.sf/en_AU/?ObjectPath=/Shops/martinandpleasance/Products/MPBHSLEEP20ML

Complaint to TGA: Martin & Pleasance Pty Ltd, Rescue Sleep Spray & Drops



10ML Rescue Sleep Drops

Product no.: MPBHSLEEP10ML

★★★★★ (1)

■ In stock

AU\$22.25

 Add to basket

 Add to shopping list  Compare

 Recommend

Lacks required information

http://store.martinandpleasance.com/epages/martinandpleasance.sf/en_AU/?ObjectPath=/Shops/martinandpleasance/Products/MPBHSLEEP10ML

Complaint to TGA: Martin & Pleasance Pty Ltd, Rescue Sleep Spray & Drops

RESCUE® Sleep is a combination of the 5 Bach™ Original Flower Remedies contained in RESCUE® Remedy, plus the Bach™ Original Flower Remedy of White Chestnut.

White Chestnut is used to help switch off the mind from unwanted, repetitive thoughts. These flower essences combine to help you enjoy a natural nights sleep:

- **Rock Rose** – for terror and panic
- **Impatiens** – for irritability and impatience
- **Clematis** – for inattentiveness
- **Star of Bethlehem** – for shock
- **Cherry Plum** – to promote calmness and mental clarity
- **White Chestnut** – to help switch off the mind from unwanted repetitive thoughts

How can RESCUE® Sleep help you with a good nights sleep?

RESCUE® Sleep can help with a natural nights sleep when your mind won't switch off from unwanted repetitive thoughts – preventing you from falling asleep. Those unwanted repetitive thoughts are often directly linked to unfulfilled and stressful events which may have happened during the day, or are due to take place the following day such as financial issues, an important presentation, a job interview, your little ones first day at a new school, the apprehension brought on by your wedding day or an upcoming flight.

Whatever the thoughts preventing you from switching off at night time might be, now that there is RESCUE® Sleep, you can look forward to waking up refreshed and energised in the morning and more importantly, be ready to face the day ahead!

RESCUE® Sleep suitable for the whole family, vegan friendly and non-drowsy.

<http://www.martinandpleasance.com/brands/rescue-remedy/about-rescue-sleep/>

Complaint to TGA: Martin & Pleasance Pty Ltd, Rescue Sleep Spray & Drops



Rescue Remedy Sleep 20ml Spray

Product ID: 2580710
★★★★★ 4.8 (15) [Write a review](#)

\$19.99

\$15.16 Off RRP
Don't Pay RRP: \$35.15

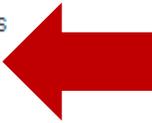
QTY:

 **ADD TO CART**

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

THIS PRODUCT MAY NOT BE RIGHT FOR YOU. ALWAYS READ THE LABEL, WARNINGS AND INSTRUCTIONS FOR USE, BEFORE PURCHASE. VITAMIN AND MINERAL SUPPLEMENTS SHOULD NOT REPLACE A BALANCED DIET.

General Information

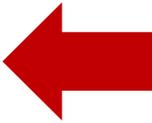
Rescue Sleep has been traditionally used to relieve sleeplessness associated with recurring and worrying thoughts. Assists with relief from anxiety, nervous tension, stress, agitation or despair and provides a sense of focus and clam. 

Rescue Sleep is a combination of Original Bach Rescue Remedy and White Chestnut.

Rescue Sleep is suitable for the whole family.

AUSTL 153231

Always read the label and use only as directed, if symptoms persists consult your healthcare practitioner.

Instructions for use:
2 sprays or 4 drops directly onto the tongue or into a glass of water (sipped at intervals). Rescue Remedy can be taken as often as required and as frequently as every 10 minutes. 

Available in 10ml dropper bottle, 20ml oral spray.

<https://www.chemistwarehouse.com.au/buy/53489/rescue-remedy-sleep-20ml-spray>

Over 75 years ago Dr Edward Bach discovered Rescue Remedy. Rescue Sleep combines Rescue Remedy with Bach Original White Chestnut flower remedy. Made by the original Bach methods. Contains ingredients of homeopathic potency. No artificial colours, flavours or preservatives. 

<https://www.priceline.com.au/rescue-rescue-sleep-10-ml>

Complaint to TGA: Martin & Pleasance Pty Ltd, Rescue Sleep Spray & Drops

Product description

Rescue Sleep Spray is a natural sleep aid made from 6 of the bach flower remedies. Rescue Sleep Spray has white chestnut for a restless mind, rock rose for relieving terror and panic, clematis for inattentiveness, cherry plum for irrational thoughts and impatience and irritation. Rescue Sleep Spray helps aid a restful night's sleep in times of stress and anxiety.

https://www.amazon.com.au/Rescue-Sleep-Spray/dp/B00NLA4GF6/ref=sr_1_4?keywords=rescue+sleep&qid=1578455502&sr=8-4

Description	Ingredients	Usage	Warnings
<p>White Chestnut: To help ease restless mind. Star of Bethlehem: For trauma and shock. Clematis: For the tendency to "pass out", and unconsciousness, being 'far away' and not present mentally. Cherry Plum: Fear of mind giving way, verge of breakdown, anger. Impatiens: For irritability, tension and fidgety. Rock Rose: For frozen terror and panic. 5x (HPUS) dilution Star of Bethlehem - Orithogalum umbellatum Rock Rose - Helianthemum Cherry Plum - Prunus cerasifera Impatiens - Impatiens glandulifera Clematis - Clematis vitalba White Chestnut - Aesculus Hippocastanum.</p>			

<https://www.goodpricepharmacy.com.au/bach-rescue-remedy-sleep-drops-10ml>

Description
<p>Rescue Sleep Spray 20ml RESCUE® Sleep Spray has been traditionally used to relieve sleeplessness associated with recurring and worrying thoughts and feelings of anxiety, nervous tension, stress or agitation. RESCUE® Sleep Spray contains the 5 Bach™ Original Flower Remedies that are also in RESCUE® Remedy. RESCUE® Sleep also contains Bach™ Original Flower Remedies of White Chestnut. Rock Rose - for terror and panic Impatiens - for irritability and impatience Clematis - for inattentiveness Star of Bethlehem - for shock Cherry Plum - to promote calmness and mental clarity White Chestnut - to help switch off the mind from unwanted repetitive thoughts These flower essences combine to help you enjoy a natural nights sleep. DIRECTIONS FOR USE: 2 sprays directly on the tongue, at intervals throughout the day.</p>
<p>Dosage: 2 sprays INGREDIENTS: Each mL contains 152mCL (equiv 15.2mCL of fresh plant) tinctures of Rock Rose (Helianthemum nummularium) Impatiens (Impatiens glandulifera) Clematis (Clematis vitalba) Star of Bethlehem (ornithogalum umbellatum) Cherry Plum (Prunus cerasifera) White Chestnut (Aesculus hippocastanum)</p>
<p>WARNING: the Label and use only as directed. If symptoms persist, consult your healthcare professional.</p>

<https://www.pharmacy4less.com.au/rescue-sleep-spray-20ml-4.html?amp=1>

Usage Instructions:

Dosage: 4 Sprays

Directions: 4 Sprays directly onto the tongue or into a glass of water (sipped at intervals).

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<https://shop.coles.com.au/a/a-national/product/bach-rescue-remedy-sleep-spray>

Homeopathic Bach flower remedy for feelings of stress. Safe for the whole family. Free from artificial additives. Suitable for vegans.

<https://mojohealth.com.au/products/martinpleasancerescueremedysleep10ml>