

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

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 Remedy Drops & spray

Sponsor: Martin & Pleasance Pty Ltd

Address: 7 Rocklea Drive Port Melbourne VIC 3207 Australia

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

ARTG: 148318

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

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

- 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:

08/01/20

URL(s) listed (screen shots appended)

- http://store.martinandpleasance.com/epages/martinandpleasance.sf/en_AU/?ObjectPath=/Shops/martinandpleasance/Products/MPBHY139

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- <https://www.rescueremedy.com/en-au/rescue-range/rescue-remedy/rescue-remedy-dropper>
- <https://www.chemistwarehouse.com.au/buy/39229/rescue-remedy-drops-20ml?rcid=932>
- https://www.amazon.com.au/Bach-Original-Flower-Remedies-Rescue/dp/B000YIA1B6/ref=sr_1_1?hvadid=270828172209&hvdev=c&hvlocphy=9071337&hvnetw=g&hvpos=1t3&hvqmt=b&hvrnd=123429587329265115&hvtargid=kwd-12276120&keywords=rescue+remedy&qid=1578445381&sr=8-1
- <https://www.goodpricepharmacy.com.au/bach-rescue-remedy-drops-20ml>
- <https://www.pharmacy4less.com.au/rescue-remedy-drops-20ml-4.html>
- <https://www.yourdiscountchemist.com.au/rescue-remedy-drops-10ml.html>
- <https://shop.coles.com.au/a/a-national/product/bach-rescue-remedy-drops>
- <https://www.catch.com.au/product/rescue-remedy-20ml-drops-1992749/?sid=rescue%20remedy&sp=2&st=32&srtrev=sj-7ea07tsscvc160qkols8aec.click>
- <https://www.ebay.com.au/itm/Rescue-Remedy-10ml-Drops-Flower-Essence-Natural-Remedy/173482843835?hash=item2864621ebb:g:LUAAOSw5r9d6Epi>
- <https://www.woolworths.com.au/shop/productdetails/769653/rescue-remedy-liquid-drops>
- <https://www.priceline.com.au/rescue-remedy-drops-10-ml>
- https://mojohealth.com.au/products/mprescueremedy20ml?_pos=1&_sid=c03ca5d62&_ss=r
- 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

Stress and anxiety are 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 Remedy drops and sprays.¹

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

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Disputed claims (screen shots appended):

The traditional claims made for Bach Rescue Remedies such as, **'relieve 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 'terror, panic, irritability and impatience, inattentiveness, shock' 'non drowsy', 'non habit forming', 'vegan' and 'Whatever the situation, immediate or ongoing RESCUE® Remedy can help' (s.9(d), 10(a)(ii) Code breach)
- Claims, 'Safe for all the 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 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 such as 'cope in balancing life's ups and downs', 'Assists the return to a more positive outlook when you need comfort and reassurance', 'Provides support in times of emotional demand, such as before a driving test, interview, exam or flight or when you simply need a little help', 'help you regain control when life leaves you a little frazzled', '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) Code breach)
- Lacks the tradition of use in the permitted indication: Traditionally used in Bach flower remedies (s.23 Code breach)
- Dose craziness, e.g. '4 drops in water and sip at intervals, or 4 drops on the tongue. Alternatively add to 30mL mixing bottle containing still spring water and take 4 drops a minimum of 4 times a day' CM.

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.

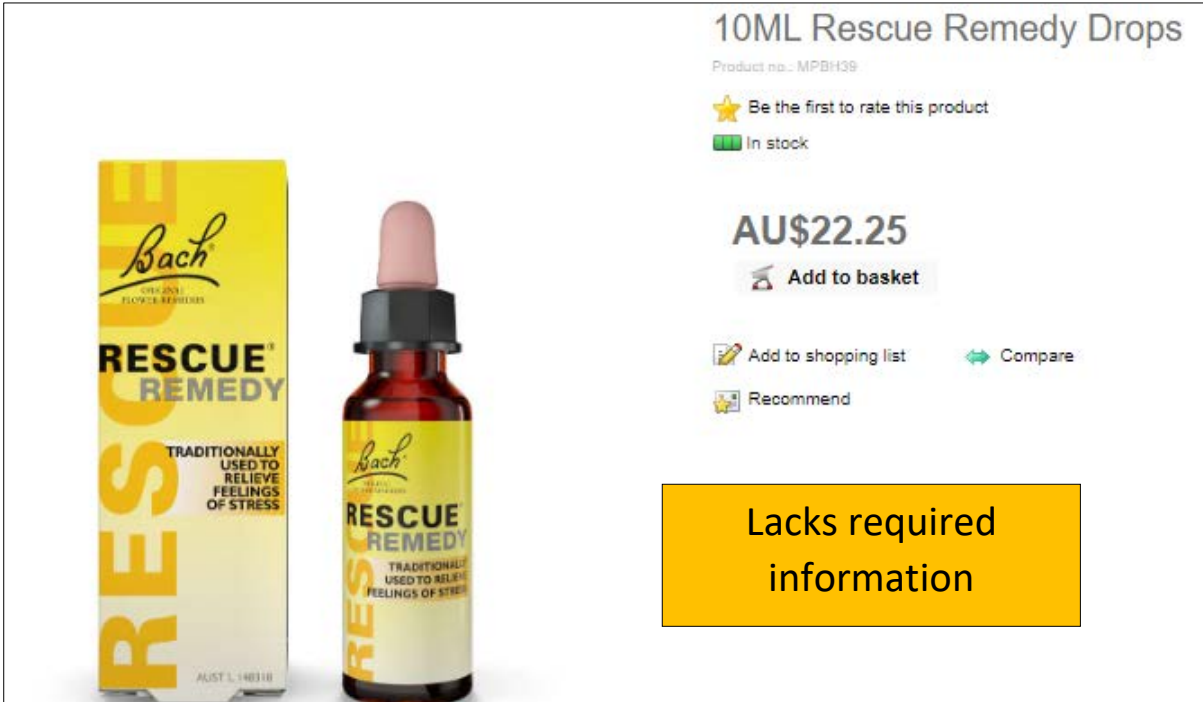
Reference	Study design	Jadad score	Validity score	Sample	Interventions	Main outcome measures	Main result	Comment
von Rühle (1995) [17]	RCT, 3 parallel groups (not placebo controlled, not double-blinded)	2	3	24 pregnant women with overdue births	Individualised flower remedies daily up to date of birth, 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/>

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Appendix II (Screen shots)



10ML Rescue Remedy Drops

Product no.: MPBH39

★ Be the first to rate this product

🟢 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/MPBH39

About Rescue Remedy

Print

RESCUE® Remedy

Over 60 years ago Dr Edward Bach recognised the need for an emergency treatment to help people cope with such everyday stressful situations and thus created RESCUE Remedy. Still made to his exact specifications today, RESCUE® Remedy has become renowned for its calming and centering effects. It is now relied upon by millions of people around the world to provide unconditional support during demanding times.

RESCUE® Remedy is a unique combination of five [Bach™ Original Flower Remedies](#) all working on emotional imbalances associated with daily stressful situations:

- **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


The [Bach™ Original Flower Remedies](#) are a complete system of 38 flower remedies that can help us rediscover the positive side of ourselves.

Whatever the situation, immediate or ongoing RESCUE® Remedy can help.

Always read the label and use only as directed. If symptoms persist, consult your healthcare professional.

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

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Rescue Remedy Drops 20mL


Product ID: 2499528
★★★★★ 5.0 (1) [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 Remedy
Helps you cope in balancing life's ups and downs. ←
Assists the return to a more positive outlook when you need comfort and reassurance. ←
Provides support in times of emotional demand such as before a driving test, interview, exam or flight or when you simply need a little help. ←
Suitable for all the family.

Ingredients

5x dilution of flower extracts of Rock Rose, Impatiens, Clematis, Star of Bethlehem, Cherry Plum in a grape alcohol solution.

Directions

4 drops in water and sip at intervals, or 4 drops on the tongue. ←
Alternatively add to 30mL mixing bottle containing still spring water and take 4 drops a minimum of 4 times a day.

<https://www.chemistwarehouse.com.au/buy/39229/rescue-remedy-drops-20ml?rcid=932>

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Bach Original Flower Remedies - Rescue Remedy - 10 ml.

by Bach

★★★★☆ 113 ratings


Lacks required information

Price: \$11.96

- Developed by a doctor more than 80 years ago, homeopathic RESCUE REMEDY was formulated to help you stress less, stay calm and in control
- A blend of five BACH ORIGINAL FLOWER REMEDIES, the original RESCUE REMEDY in the iconic little yellow bottle has provided gentle, non-habit forming stress relief to millions around the world for generations.
- Dr. Bach developed his original blend of flower remedies €" Rock Rose, Impatiens, Clematis, Star of Bethlehem, and Cherry Plum €" to help you regain control when life leaves you a little frazzled.
- Support your wellbeing and harness the positive potential of RESCUE REMEDY by simply adding 4 drops to a drink of your choice or put 4 drops on your tongue as often as required.
- Gentle, non-habit forming every day natural stress relief. Homeopathic, gluten free, easy to use. Safe for the whole family.

https://www.amazon.com.au/Bach-Original-Flower-Remedies-Rescue/dp/B000YIA1B6/ref=sr_1_1

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Rescue Remedy Drops 20MI
RRP \$31.99 - Save 9% or \$3.00 off RRP
\$28.99

RATINGS:

AVAILABILITY:
In store and online

- 0 + **OUT OF STOCK**

Lacks required information

<https://www.pharmacy4less.com.au/rescue-remedy-drops-20ml-4.html>

Dosage:

4 drops

Directions:

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

Size:

20ml

Warning:

Always read the label and use only as directed. If symptoms persist, consult your healthcare professional. Contains homeopathic ingredients. **←** Alcohol.

<https://www.catch.com.au/product/rescue-remedy-20ml-drops-1992749/?sid=rescue%20remedy&sp=2&st=32&sortrev=sj-7ea07tsscv160qkols8aec.click>

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

https://mojohealth.com.au/products/mprescueremedy20ml?_pos=1&_sid=c03ca5d62&_ss=r