Bach Flower Remedies Ltd.

Product Information And Usage Guidance Sheet

1. TRADE NAME OF THE MEDICINAL PRODUCT

Rescue Remedy - 10, 20 ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

5X (HPUS) Rescue Concentrate* in a grape alcohol solution (27% v/v alcohol).

*Rescue Concentrate is an alcoholic solution which contains extracts of five plants as follows:-

Rock Rose (Helianthemum nummularium) Cherry Plum (Prunus cerasifera) Impatiens (Impatiens glandulifera) Star of Bethlehem (Ornithogalum umbellatum) Clematis (Clematis vitalba)

3. PHARMACEUTICAL FORM

Liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

A Homeopathic Remedy for Natural Stress Relief.

4.2 Posology and method of administration

Adults and children over 12 years: Take 4 drops in a small glass of water, repeat dose as necessary. Can also be taken by placing 4 drops directly on the tongue.

Consult a physician for use in children under 12 years of age.

4.3 Contra-indications

Known hypersensitivity to any of the ingredients.

All Bach Flower Remedies contain alcohol and may be unsuitable for persons receiving certain types of medication.

We recommend that all persons who have been advised to avoid alcohol while receiving such medication should consult a pharmacist, Doctor, or qualified health professional before taking any Bach Flower Essence.

Persons receiving medication to counteract alcohol addiction should not use Bach Flower Essences in any form or dilution.

4.4 Special warnings and special precautions for use

Keep out of reach of children. **If pregnant or breast-feeding**, consult a pharmacist, Doctor, or qualified health professional before use.

4.5 Interaction with other medicaments and other forms of interaction

As for contra-indications.

4.6 Pregnancy and lactation

As with many other medicaments, use during this period is at the physician's discretion. **If pregnant or breast-feeding**, consult a pharmacist, Doctor, or qualified health professional before use.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Not known.

4.9 Overdose

Not known.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable. Used in accordance with tradition.

5.2 Pharmacokinetic properties

Not applicable. Used in accordance with tradition.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

27% Grape alcohol.

6.2 Incompatibilities

Not known. Whilst Bach Flower Essences are considered to be a safe form of treatment, they do contain alcohol. If you are taking a medicine which is contra-indicated with alcohol, speak to a pharmacist, Doctor or qualified health professional before use.

6.3 Shelf Life

60 months.

6.4 Special precautions for storage

No special storage conditions required. It is recommended that the product is stored in a cool dry place, and out of direct sunlight.

6.5 Nature and contents of container

Container: Amber glass (type I) vial, with glass pipette, natural rubber bulb (European Pharmacopoeia) and polypropylene plastic cap. 10 ml, 20 ml.

6.6 Instructions for use/handling

None specified.

7. MARKETING AUTHORISATION HOLDER

A. Nelson & Co. Ltd. 5-9 Endeavour Way Wimbledon London SW19 8UH UK

Distributed by: Nelson Bach USA Ltd. Wilmington MA 01887.

8. NATIONAL DRUG CODE

NDC 057687-239-10. NDC 057687-239-20.

9. DATE OF (PARTIAL) REVISION OF THE TEXT

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Kyle Long Global Suybmission Officer

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