6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose (capsule shell)

6.2 Incompatibilities

Not Applicable.

6.3 Shelf-life

3 years.

6.4 Special Precautions for storage

Store below 25°C. Store in the original package.

6.5 Nature and contents of container

Duma 110ml HDPE plastic container and tamper evident threaded Duma cap.

PASSIFLORA pack contains 60 Capsules.

6.6 Special precautions for disposal

There are no special precautions for disposal of PASSIFLORA capsules. When the container is empty the label should be removed and the container placed in a recycling bin.

7 MARKETING AUTHORISATION HOLDER

Kerbina Limited,
Trading as:

Bio-Health Limited
Culpeper Close
Medway City Estate
Rochester
Kent
ME2 4HU

8 MARKETING AUTHORISATION NUMBER(S)

THR 00904/0001

9 DATE OF REGISTRATION

05/08/11

10 DATE OF REVISION

05/08/11

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BIO-HEALTH®

PASSIFLORA HERB CAPSULES

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Passiflora
Summary of Product Characteristics

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1 NAME OF THE MEDICINAL PRODUCT

PASSIFLORA Herb Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 300mg of Passion Flower herb (*Passiflora incarnata* L.).

For list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsules.
Clear size 0 hard capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

PASSIFLORA Herb Capsules is a traditional herbal medicinal product used for the temporary relief of mild anxiety and to aid sleep, based on traditional use only.

4.2 Posology and method of administration

For oral, short term use only use only.

For adults and the elderly.
For the temporary relief of symptoms of mild anxiety take 1-2 capsules 3 times a day.

To aid sleep, take 2 capsules 30 minutes before bedtime with an earlier dose of 2 capsules earlier in the evening if necessary.

Swallow the capsules with a glass of water.
Maximum daily dose: 8 single doses

Duration of use:-
If symptoms persist, worsen or do not improve after 4 weeks during the use of the product, a doctor or a qualified healthcare practitioner should be consulted.

The use of this product in children and adolescents under 18 years of age is not recommended (see Section 4.4 Special Warnings and Precautions for use).

4.3 Contra-indications

Hypersensitivity to Passion Flower or any of the excipients.

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4.4 Special Warnings and Precautions for Use

Do not exceed the stated dose.

If symptoms persist, worsen or do not improve after 4 weeks during the use of the product, a doctor or a qualified healthcare practitioner should be consulted.

The use of the product in children and adolescents under 18 years of age is not recommended as data is not sufficient and medical advice should be sought.

4.5 Interaction with other medicaments and other forms of interaction

Concomitant use with synthetic sedatives such as benzodiazepines is not recommended unless advised by a doctor.

4.6 Fertility, Pregnancy and Lactation

The safety of the product during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. Tests on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

The product may impair the ability to drive ands use machines.
Affected patients should not drive or operate Machinery.

4.8 Undesirable effects

One case of hypersensitivity (vasculitis) and one case of nausea and tachycardia have been reported.
The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or qualified health care practitioner should be consulted.

4.9 Overdose

No case of overdose has been reported. Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Not required as per Article 16c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic Properties

Not required as per Article 16c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Test on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

Passiflora
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