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 in the original package.

6.5 Nature and contents of container

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

Duma 200ml HDPE plastic container and tamper evident Duma cap.

PERIAGNA pack contains 60 or 120 Capsules.

6.6 Special precautions for disposal

There are no special precautions for disposal of PERIAGNA capsules.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

THR 15817/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/02/2011

10 DATE OF REVISION OF THE TEXT

04/02/2011

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BIO-HEALTH®

Periagna®

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Periagna
Summary of Product Characteristics

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1 NAME OF THE MEDICINAL PRODUCT

PERIAGNA

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 400mg of Agnus Castus fruit (*Vitex agnus castus* 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

PERIAGNA is a traditional herbal medicinal product used to help relieve premenstrual symptoms such as irritability, mood swings, breast tenderness, bloating and menstrual cramps, based on traditional use only.

4.2 Posology and method of administration

For oral use only. For women experiencing premenstrual symptoms.

For the temporary relief of symptoms associated with premenstrual syndrome. Take 1 capsule 2 times a day, morning and night, swallowed with water.

As treatment effects may not be apparent immediately, the product may need to be taken up to 3 months continuously.
Maximum daily dose:- 2 capsules.

Duration of use:-
If symptoms persist, worsen or do not improve after 3 months use of PERIAGNA, a doctor or a qualified healthcare practitioner should be consulted.

Women suffering a pituitary disorder should not take the product (see section 4.3).

The use 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 Agnus castus or any of the excipients.
This product should not be used by women with a pituitary disorder.
This product is not recommended for use in children or adolescents under 18 years of age.
The safety of agnus castus during pregnancy and lactation has not been established. Therefore this product must not be used during pregnancy or lactation.

4.4 Special Warnings and Precautions for Use

Patients who suffer or suffered from an oestrogen-sensitive cancer should consult their doctor before using the product.

Patients who are using dopamine agonists, dopamine antagonists, oestrogens and antioestrogens should consult their doctor before using the product (see section 4.5 'Interactions with other medicinal products and other forms of interaction').

The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.

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If the symptoms worsen during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

Vitex agnus-castus fruits are thought to act on the pituitary-hypothalamic axis and therefore patients with a history of a pituitary disorder should consult with a doctor before using this product. In cases of prolactin secreting tumours of the pituitary gland the intake of *Vitex agnus-castus* fruits can mask symptoms of the tumour.

4.5 Interaction with other medicaments and other forms of interaction

Because of the possible dopaminergic and oestrogenic effects of *Vitex agnus-castus* fruits interactions with dopamine agonists, dopamine antagonists, oestrogens and antioestrogens cannot be excluded.

4.6 Pregnancy and Lactation

There is no indication for the use during pregnancy.
Data from reproductive studies suggest that extracts of the fruits may affect lactation. The use during lactation is not recommended.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Severe allergic reactions with face swelling, dyspnoea and swallowing difficulties.
(Allergic) skin reactions (rash and urticaria), headache, dizziness, gastrointestinal disorders (such as nausea, abdominal pain), acne, menstrual disorders have been reported.
The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

4.9 Overdose

No case of overdose has been reported.

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

Tests on mutagenicity and carcinogenicity have not been performed.
Limited data from reproductive studies suggest that extracts of the fruits influence lactation.
Adequate tests on reproductive toxicity have not been performed.

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