6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other core ingredients: Sucrose, Lactose monohydrate, Talc, Magnesium Stearate, Sodium Starch Glycollate, Cayenne, Native extract, Maltodextrin, Colloidal anhydrous silica.

Coating Ingredients: Titanium Dioxide (E171), Iron Oxide Black (E172), Syrup.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

36 months.

Shelf life after first opening the container: 12 months.

6.4 Special Precautions for storage

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

6.5 Nature and contents of container

Plastic container with tamper evident cap – 60 tablets.
Plastic container with tamper evident cap – 30 tablets

6.6 Special precautions for disposal

There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER

Kerbina Limited T/A
Bio-Health Limited
Culpeper Close
Medway City Estate
Rochester
Kent. ME2 4HU

8 MARKETING AUTHORISATION NUMBER(S)

THR 00904/0002

9 DATE OF REGISTRATION

10 DATE OF REVISION

Bio-Health Ltd. Culpeper Close, Medway City Estate, Rochester, Kent ME2 4HU
t +44 (0)1634 290 115 **f** +44 (0)1634 290 761 **e** info@bio-health.co.uk **w** www.bio-health.co.uk

BIO-HEALTH®

Lowater®

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Lowater
Summary of Product Characteristics

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1 NAME OF THE MEDICINAL PRODUCT

LOWATER®

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each coated tablet contains:
30mg of extract (as dry extract) from Buchu leaf (Agathosma betulina (Berg) Pillans (ratio 4:1).
Extraction solvent: Ethanol 70% / Water 30%.

30mg of extract (as dry extract) from Uva Ursi leaf (*Arctostaphylos uva-ursi* (L.) Spreng. (ratio 2·5 - 4·5:1).
Extraction solvent: Water 100%.

50mg of extract (as dry extract) from Dandelion root (ratio 3·5:1) (Taraxacum officinale Weber).
Extraction solvent: Ethanol 60% v/v.

Each tablet contains 228mg of sucrose and 68mg lactose.

See section 4.4 special warnings and precautions for use.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Grey bi-convex coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used to relieve bloating associated with premenstrual water retention, based on traditional use only.

4.2 Posology and method of administration

For oral use only.

Adults: 2 tablets to be taken in the morning and 2 tablets in the evening. The tablets should be taken before the period is expected to start.

The use in children and adolescents under 18 years of age and the elderly is not recommended (see section 4.4 Special Warnings and Precautions for Use.)

Duration of use:-
If symptoms worsen or persist after using the product, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active substances or plants of the Asteraceae (Compositae) or to any of the excipients.
Obstructions of the bile ducts, cholangitis, liver diseases, gallstones, active peptic ulcer and other biliary diseases.

4.4 Special Warnings and Precautions for Use

Do not exceed the stated dose.

If symptoms worsen or do not improve after one week or if symptoms such as fever, spasm, dysuria or blood in the urine occur, a doctor or qualified healthcare practitioner should be consulted.

The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data. The use in the elderly is not relevant to the indication.

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The use in patients with renal failure and/or diabetes, and/or heart failure should be avoided because of possible risks due to hyperkalaemia.

Contains lactose monohydrate and sucrose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Additive effects with diuretics cannot be excluded and therefore concomitant treatment is not recommended.

4.6 Fertitlity, Pregnancy and Lactation

Safety during pregnancy and lactation has not been established. Due to the lack of data, 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

No studies on the effects on the ability to drive or operate machines have been performed.

4.8 Undesirable effects

Epigastric pain and hyperacidity may occur. The frequency is not known.

Allergic reactions may occur. The frequency is not known.

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

4.9 Overdose

No cases of overdose have 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 reproductive toxicity , genotoxicity and carcinogenicity have not been performed.

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