PROFESSIONAL INFORMATION

1. NAME OF THE MEDICINAL PRODUCT

Bronchostop Nite

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml oral solution contains:

62.5 mg Marshmallow root dry extract (*Althaeae officinali*s L), DER 7-9:1
45.5 mg Lime flower dry extract (*Tilia cordata Miller, Tilia platyphyllos Scop., Tilia x vulgaris Heyne* or their mixtures) (DER 3-8:1)
50.0 mg Ribwort plantain leaf dry extract (*Plantago lanceolata L.*) (DER 4-6:1)

Contains sugar: glycerol 0,13 g and xylitol 0,92 g

Preservatives:
Methyl-4-hydroxybenzoate (E 218) 0,069 % *w/w*
Propyl-4-hydroxybenzoate (E 216) 0.041 % *w/w*

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
Brown opaque liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product for the relief of dry cough as well as night-time cough, pharyngeal irritation, and early symptoms of a common cold.

The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

This medicinal product is indicated for use in adults, adolescents and children from 4 years of age.

4.2 Posology and method of administration

Start at the early signs of common cold.
Use the dosage cap provided.

Posology
Adults and adolescents aged 12 years and above:
15 ml (up to 4 times daily (maximum daily dose up to 60 ml). The last dose should be taken directly before bedtime.

Paediatric population

Children from 4 to 11 years of age:
7.5 ml 3 to 4 times daily (maximum daily dose up to 30 ml). The last dose should be taken directly before bedtime.

Children under 4 years:
Due to lack of adequate data the use in children below 4 years is not recommended (see section 4.4).

Method of administration
For oral use.
The medicinal product is taken undiluted. It is recommended not to drink and/or eat for 30 minutes to 1 hour after intake.

Duration of use
If the symptoms worsen or persist longer than 7 days during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If the symptoms worsen during the use of the medicinal product or if dyspnoea, high fever or purulent sputum occurs, a doctor or a qualified healthcare professional should be consulted.

Absorption of concomitantly administered medicines may be delayed. As a precautionary measure, this medicinal product should not be taken 30 minutes to 1 hour before or after taking other medicines.

Paediatric population
The use in children under 4 years of age is not recommended due to lack of data.

This medicinal product contains glycerol and xylitol which may have an effect on the control of blood sugar in patients with *diabetes mellitus*. Patients with the rare hereditary condition of glycerol/xylitol intolerance should not take Bronchostop Nite.
This medicinal product contains 11.04 g xylitol in the maximum daily dose. It may therefore have a laxative effect. The calorific value is 2.4 kcal/g xylitol.

This medicinal product contains methyl-parahydroxybenzoate and propyl-parahydroxybenzoate. These preservatives may cause allergic reactions (possibly delayed).

This medicinal product contains propylene-glycol and benzyl alcohol.. Benzyl alcohol may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions are not known.
No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy and breast-feeding
Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Fertility
Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

None known.

If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000. Website: www.inovapharma.co.za.

4.9 Overdose

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other cough suppressants
ATC code: R05DB

The polysaccharides contained in marshmallow root and ribwort plantain relieve oral or pharyngeal irritation and thus the urge to cough during the day as well as during the night. The ingredients of lime flower promote sweating and thereby relieve feverish colds.

5.2 Pharmacokinetic properties

No pharmacokinetic studies have been performed.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans.

In tests on genotoxicity (Ames tests) with the herbal preparations contained in the medicinal product no mutagenicity was observed.

Tests on developmental and reproductive toxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltodextrin
Silica colloidal anhydrous
Glycerol
Xylitol (E 967)
Methyl-parahydroxybenzoate (E 218),
Propyl-parahydroxybenzoate (E 216),
Citric acid monohydrate (for pH-adjustment)
Xanthan gum
Strawberry flavour (contains benzyl alcohol (E 1519), propylene-glycol (E 1520))
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
After first opening: 2 months

6.4 Special precautions for storage

After first opening, do not store above 25 °C.
Keep the container tightly closed after use.
Keep in original packaging in order to protect from light.

6.5 Nature and contents of container

Brown glass bottles with tamper evidence ring, with nozzle and polyethylene screw cap packed in a carton box.
Polypropylene dosage cap with 2.5 ml to 20 ml scale.
Pack sizes: 120 ml
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6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007
Tel: (011) 087 0000
www.inovapharma.co.za

8. MARKETING AUTHORISATION NUMBER(S)

To be allocated.
Complementary Medicine: Discipline Specific Traditional Claims.
D33.7 Combination product.

This unregistered medicine has not been evaluated by SAHPRA (South African Health Products Regulatory Authority) for its quality, safety or intended use.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: To be allocated.

10. DATE OF REVISION OF THE TEXT

May 2023