Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bronchosan dry, tickly cough syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5 ml (6.95 g) of syrup contains 1,445 mg of extract (as soft extract) from *Picea abies* (L.) Karsten (Norway Spruce) shoots (0.9 - 1.2:1). Extraction solvent: water.

Excipients with known effect:
Each 5 ml of syrup contains 5.25 g of sugar mainly present as sucrose, glucose and fructose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup
It is a brown syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product for the relief of coughs, such as dry, tickly, irritating coughs exclusively based on long-standing use.
This medicine is indicated for use in adults and adolescents over 12 years.

4.2 Posology and method of administration

Posology
Adults and adolescents over 12 years:
5-10 ml 2-4 times daily
The use in children below 12 years of age is not recommended (see 4.4 Special warnings and precautions for use).

Method of Administration

If symptoms worsen or do not improve during the use of Bronchosan or persist for more than 7 days, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

For oral short-term use only.

4.3 Contraindications

Hypersensitivity to the active ingredient, Pine species, colophony or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If symptoms worsen or do not improve during the use of Bronchosan or persist for more than 7 days a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

If dyspnoea, fever or purulent sputum occurs a doctor should be consulted.

Contains sucrose as well as sources of glucose and fructose (honey and concentrated pear juice). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The additive effect of concomitantly administered products containing fructose (or sorbitol) and dietary intake of fructose (or sorbitol) should be taken into account.

Contains 5.25 g of sugar per 5 ml dose. This should be taken into account in patients with diabetes mellitus.

The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.

Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established, therefore the use of this product during pregnancy and 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

Very rare (<1/10,000)

Skin and subcutaneous tissue disorders:
- Pruritis
- Rash

If other adverse reactions not mentioned above occur, a qualified healthcare professional e.g. a doctor or pharmacist 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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

There are no data on human overdose with spruce. Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article16c (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 and carcinogenicity have not been performed with this product.
No mutagenic effects of Bronchosan were detected in Ames' test (with or without metabolic activation).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Raw cane sugar (containing sucrose)
Honey (containing sucrose, fructose and glucose)
Concentrated pear juice (containing sucrose, fructose and glucose)
Pine oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottle (Ph. Eur. type III glass) with white pilfer-proof high density polyethylene screw cap. A measuring cup with a 2.5, 5, 10, 15 and 20 ml measure is supplied with this pack.

Pack sizes: 100 ml and 200 ml
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

A. Vogel Ireland Ltd,
Unit 3D, Killeen Road,
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8 REGISTRATION NUMBER(S)

TR2309/008/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 7th of March 2014
Date of last renewal: 6th March 2019

10 DATE OF REVISION OF THE TEXT

September 2022