

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bronchoforce chesty cough oral drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 20 drop dose contains:

198 mg of tincture from *Hedera helix* L. (fresh Ivy herb) (1: 5.7 – 6.0)

Extraction solvent: Ethanol 51 % v/v

173 mg of tincture from *Thymus vulgaris* L. (fresh aerial parts of Thyme) (1: 8.0 – 8.2)

Extraction solvent: Ethanol 51 % v/v

123 mg of tincture from *Glycyrrhiza glabra* L. (Licorice root) (1: 10 – 11).

Extraction solvent: Ethanol 51 % v/v

1 ml is equivalent to 38 drops

Excipient with a known effect: A maximum dose of 20 drops contains approximately 212 mg of ethanol (alcohol).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution.

It is a clear brown liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used as an expectorant for the relief of chesty coughs associated with cold, 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: Take 20 drops 3-5 times daily

The use is not recommended in children under 12 years of age (see 4.4 Special warnings and precautions for use).

Duration of use

If symptoms persist, worsen or do not improve after 7 days use of Bronchoforce a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Method of administration

For oral short-term use only.

4.3 Contraindications

Hypersensitivity to ivy, thyme or liquorice preparations or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed stated dose.

The use is not recommended in children under 12 years of age because no data on safety are available.

If symptoms persist, worsen or do not improve after 7 days use of Bronchoforce a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

If dyspnoea, fever or purulent sputum occurs, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Patients taking liquorice medication should not take other liquorice containing products as serious adverse events may occur such as hypokalemia, hypertension and cardiac rhythm disorders.

Liquorice medication should be used with caution in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalemia, as they are more sensitive to the adverse effects of liquorice.

Concomitant use with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance is not recommended (see section 4.5).

Caution is recommended in patients with gastritis or gastric ulcer.

This product contains 51 vol% ethanol (alcohol). This corresponds to:

- 212 mg alcohol equivalent to 5.4 ml beer or 2.25 ml wine (per 20 drop dose)

Harmful for those suffering from alcoholism. To be taken into account in pregnant, or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

Liquorice root may counteract antihypertensive action of prescribed medicines.

Not to be used concomitantly with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance (see section 4.4).

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole).

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of Bronchoforce in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Bronchoforce is not recommended during pregnancy.

It is unknown if Bronchoforce or its metabolites are excreted in human milk. A risk to newborns cannot be excluded. Bronchoforce should therefore not be used during breast-feeding.

Studies on fertility have not been performed.

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.

This product contains alcohol (See Section 4.4 for details of alcohol content).

4.8 Undesirable effects

Gastrointestinal symptoms (e.g. nausea, vomiting and diarrhoea), skin hypersensitivity reactions, hypokalemia, hypertension, cardiac rhythm disorders and hypertensive encephalopathy may occur. The frequency is not known.

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 HPRC 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

No case of overdose has been reported.

Cases of overdose have been reported with prolonged use (more than 4 weeks) and/or intake of large amounts of liquorice. Symptoms include water retention, hypokalemia, hypertension, cardiac rhythm disorders and hypertensive encephalopathy.

Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (20.4 g in 50 ml: 40.8 g in 100 ml: equivalent to 2 or 4 large glasses of wine, respectively) may result in intoxication and should be treated accordingly.

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

A study has shown that 18 β -glycyrrhetic acid¹ crosses through the placental barrier and can be detected in the rat foetuses. Following feeding of dams with 100 mg 18 β -glycyrrhetic acid/kg/day commencing on the 13th day of gestation, on the 17th, 19th and 21st days of gestation the maternal plasma 18 β -glycyrrhetic acid concentrations were approximately 100 μ g/ml, whereas the foetal concentrations were 5, 18 and 32 μ g/ml, respectively.

In developmental toxicity studies, glycyrrhizin (ammonium salt) exhibited some embryotoxicity to the developing rat foetus, but the foetal effects were considered as minor. These effects were shown at the dose of 100 and 250 mg/kg of ammonium glycyrrhizin from 7th to 20th day of pregnancy (soft-tissue abnormalities, mostly renal, and external haemorrhages) and at the dose of 1000 mg/kg of 18 β -glycyrrhetic acid from the 13th day of gestation (significant reduction in

lamellar body content of lungs and reduced number alveolar lamellar body and surfactant clusters, but no apparent increase in malformation or foetal death rate).

Another study suggested that 100 mg/kg of liquorice extract repeated for 7 days may also aggravate body weight loss and malformations of foetuses, induced by intrauterine exposure to cyclophosphamide.

No mutagenic effects of Bronchoforce were detected in an Ames' test (with or without metabolic activation).

Tests on reproductive toxicity and carcinogenicity of the product have not been performed.

¹Where herbal preparations from *Liquiritiae radix* are used, the total exposure to 18 β -glycyrrhizic acid should be considered from a safety standpoint.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Star anise oil
Eucalyptus oil

From Tinctures
Ethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 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 dropper bottles (Type III glass) with a two-part dropper (PE-LD) / dispenser cap (PP) and ring (PE-HD)

Pack sizes: 15 ml

50 ml

Amber glass bottles (type III conforming to Ph. Eur. standards) with a two part dropper (PE-LD) / child-resistant closure (PP/PE-HD or HDPE/HDPE).

Pack sizes: 15 ml

50ml

100 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 REGISTRATION HOLDER

A. Vogel Ireland Limited
48 Upper Drumcondra Road
Dublin 9
Ireland

8 REGISTRATION NUMBER(S)

TR2309/010/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 27th February 2015.

10 DATE OF REVISION OF THE TEXT

November 2018