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. herba (fresh Ivy herb) (1: 5.7 – 6.0)
Extraction solvent: Ethanol 51 % v/v
173 mg of tincture from *Thymus vulgaris* L. herba (fresh aerial parts of Thyme) (1: 8.0 – 8.2)
Extraction solvent: Ethanol 51 % v/v
123 mg of tincture from *Glycyrrhiza glabra* L. radix (Liquorice 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 (oral drops)
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, to plants of the Araliaceae or Lamiaceae (Labiatae) families, 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 water retention, hypokalaemia, 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).

This medicine contains 212 mg of alcohol (ethanol) in each 20 drop dose. The amount in each 20 drop dose of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

4.5 Interaction with other medicinal products and other forms of interaction

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

Acute hypersensitivity reactions (including anaphylactoid reactions, such as oromucosal swelling, Quincke's oedema, dyspnoea, pruritis, urticaria, rash or anaphylactic shock) have been reported in association with use of medicinal products containing thyme or ivy, in some cases, in patients with a history of allergy/asthma. The frequency of these reactions is not known.

Gastrointestinal symptoms (e.g. nausea, vomiting and diarrhoea), hypokalaemia, 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 HPRA Pharmacovigilance, Website: www.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 ivy leaf can provoke nausea, vomiting, diarrhoea and agitation.

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 100ml: 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 18β-glycyrrhetinic acid[1] crosses through the placental barrier and can be detected in the rat foetuses. Following feeding of dams with 100 mg 18β-glycyrrhetinic acid/kg/day commencing on the 13th day of gestation, on the 17th, 19th and 21st days of gestation the maternal plasma 18β-glycyrrhetinic acid concentrations were approximately 100 microgram/ml, whereas the foetal concentrations were 5, 18 and 32 microgram/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 18β-glycyrrhetinic 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.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Star anise oil
Eucalyptus oil

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 Ltd,
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D10 TY20
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8 REGISTRATION NUMBER(S)

TR2309/010/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 27th February 2015

Date of last renewal: 26th February 2020

10 DATE OF REVISION OF THE TEXT

August 2022