

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Echinaforce Hot Drink Cold and Flu Echinacea concentrate for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5 ml of concentrate contains:

1140 mg of extract (as tincture) of fresh *Echinacea purpurea* (L.) Moench herb (1:12-13) and 60 mg of extract (as tincture) of fresh *Echinacea purpurea* (L.) Moench root (1:11-12).

Extraction solvent: Ethanol 65% V/V

Excipients with known effect:

5 ml of concentrate contains 3.22 g of sucrose and a maximum of 33 mg of ethanol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for oral solution.

Dark red to dark violet viscous liquid with an aromatic, fruity, elderberry-like odour and an aromatic, fruity, sweet, slightly sour taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used to relieve common cold and flu-like symptoms, exclusively based on long-standing use.

This product is indicated for use in adults and adolescents over 12 years.

4.2 Posology and method of administration

Posology

Adults, older people and adolescents over 12 years :

Days 1-3: Take 5 ml diluted in hot water five times daily

Days 4-10: Take 5 ml diluted in hot water three times daily

Dilute in hot water before use.

Start at first signs of common cold.

If symptoms persist, worsen or do not improve after 10 days use of this product, a qualified health care professional e.g. a doctor or pharmacist should be consulted.

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

Method of administration

For oral short-term use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance, to plants of the Asteraceae (Compositae) family or to any of the excipients listed in section 6.1.

Because of their immuno-modulatory activity, Echinacea extracts must not be used in cases of progressive systemic disorders (tuberculosis, sarcoidosis), autoimmune diseases (e.g. collagenoses, multiple sclerosis), immunodeficiencies (e.g. HIV infection, AIDS), immunosuppression (e.g. oncological cytostatic therapy, history of organ or bone marrow transplant) and diseases of the white blood cell system (e.g. agranulocytosis, leukemias).

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If the symptoms worsen or high fever occurs during the use of the product, or if symptoms persist for more than 10 days, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using Echinacea.

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

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This product contains small amounts of ethanol (alcohol), less than 100mg per dose.

4.5 Interaction with other medicinal products and other forms of interactions

This product should not be used concomitantly with immunosuppressant medications.

4.6 Fertility, pregnancy and lactation

There are no or limited data from the use of Echinaforce Hot Drink Concentrate in pregnant women.

In the absence of sufficient data, the use in 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

Hypersensitivity reactions (rash, urticaria, Stevens-Johnson Syndrome, angioedema of the skin, bronchospasm with obstruction, asthma and anaphylactic shock) may occur.

Echinacea can trigger allergic reactions in atopic patients. Association with autoimmune diseases (multiple sclerosis, erythema nodosum, immunothrombocytopenia, Evans Syndrome, Sjögren's Syndrome with renal tubular dysfunction) has been reported

The alkylamides present in Echinaforce Hot Drink Concentrate can affect the buccal mucosa which may be experienced as tingling, irritation and numbness in the mouth, this is however considered to be part of the clinical effect.

The frequency of the listed side effects is not known.

If other adverse actions not mentioned above occur, 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

No case of overdose has 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

Echinacea purpurea herb showed no toxicity in single-dose toxicity and repeated-dose toxicity studies. Tests on reproductive toxicity have not been performed with *Echinacea purpurea* herb.

Tests on repeat-dose toxicity, reproductive toxicity and carcinogenicity have not been performed with *Echinacea purpurea* root.

No mutagenic effects of Echinaforce were detected in Ames testing (with or without metabolic activation).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Purified water
Concentrated elderberry juice
Citric acid monohydrate
Modified starch
Medium-chain triglycerides
Potassium sorbate
Ethanol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months unopened.

Use within 1 month of opening. After opening, store in the refrigerator (below 8 °C).

6.4 Special precautions for storage

Store below 25 °C.

For storage conditions after first opening, see section 6.3.

6.5 Nature and contents of container

Amber glass bottle with white pilfer-proof PE-HD screw cap and a PP measuring device.

A measuring spoon with a 5ml measure is supplied with this pack

Pack size: 100 ml

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

7 REGISTRATION HOLDER

A. Vogel Ireland Limited
48 Upper Drumcondra Road
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8 MARKETING AUTHORISATION NUMBER

TR2309/009/005

8 REGISTRATION NUMBER(S)

TR2309/009/005

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of First registration: 7th of October 2016.

10 DATE OF REVISION OF THE TEXT

October 2018