Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Echinaforce Cold & Flu tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
5.9 mg of dry extract from *Echinacea purpurea* (L.) Moench herba (equivalent to 100 mg – 200 mg of fresh *Echinacea purpurea* (L.) Moench herba) (Purple coneflower herb) Extraction solvent: ethanol 65% v/v and 0.3 mg of dry extract from *Echinacea purpurea* (L.) Moench radix (equivalent to 5.6 mg – 9.8 mg of fresh *Echinacea purpurea* (L.) Moench radix) (Purple coneflower root) Extraction solvent: ethanol 65% v/v

Excipients with known effect:
One tablet contains 232.55 mg of lactose monohydrate

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Tablets.
Greenish, round-shaped, bi-convex, bevelled tablet

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 of age.

4.2 Posology and method of administration

Posology

Adults, elderly and adolescents over 12 years:
2 tablets two to five times daily

Start at first signs of common cold.

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

If symptoms persist, worsen or do not improve after 10 days use of this product, 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

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 lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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 Cold & Flu tablets 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 effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Hypersensitivity reactions (rash, urticarial, 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 syndrome with renal tubular dysfunction) has been reported.

The alkylamides present in Echinaforce Cold &Flu tabletscan 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 reactions 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 suspecteda dverse reactions via HPRA Pharmacovigilance, EarlsfortTerrace, 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(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(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

Lactose Monohydrate
Pregelatinised Starch
Magnesium Stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 3 years
Use within 3 months of opening.

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 bottles (Ph. Eur. Type III) with coated aluminium foil sealing and aluminium pilfer-proof closure fitted with a polyethylene liner.

Pack sizes: 42, 60 and 120 tablets

Not all packs sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 REGISTRATION HOLDER

A. Vogel Ireland Ltd,
Unit 3D, Killeen Road,
Dublin 10,
D10 TY20,

Ireland

8 REGISTRATION NUMBER(S)

TR2309/009/004

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 5th November 2012
Date of last renewal: 4th November 2017

10 DATE OF REVISION OF THE TEXT

May 2022