

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Echinaforce Cold and Flu chewable tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

5.9 mg of dry extract from *Echinacea purpurea* (L.) Moench herba (equivalent to 100 – 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 – 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 269.45 mg of sorbitol and 2.1 mg of orange flavour (containing sucrose).

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Chewable tablet

Greenish, flat, round-shaped, speckled 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, older people and adolescents over 12 years: Chew 2 tablets two to three times daily.

To be chewed.

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 Echinaforce, 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.

This medicine contains sorbitol. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take this medicinal product.

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

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

#### **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 chewable 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, 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, Sjörger syndrome with renal tubular dysfunction) has been reported.

The alkylamides present in Echinaforce Cold & Flu chewable tablets 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 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 suspected adverse reactions via HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto: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**

Sorbitol  
Betadex  
Colloidal Anhydrous Silica  
Orange flavour (containing sucrose)  
Magnesium stearate

#### **6.2 Incompatibilities**

Not applicable.

#### **6.3 Shelf life**

Unopened: 3 years  
Use within 2 months of opening.

#### **6.4 Special precautions for storage**

Store in the original container to protect from moisture.

This medicinal product does not require any special temperature storage conditions.

#### **6.5 Nature and contents of container**

Amber glass bottles (Ph. Eur. Type III) with PE stopper caps containing a molecular sieve as desiccant.  
Pack sizes: 40, 80 and 120 tablets

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

Pack sizes: 40, 80 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 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  
Dublin 9  
Ireland

**8 MARKETING AUTHORISATION NUMBER**

TR2309/009/003

**8 REGISTRATION NUMBER(S)**

TR2309/009/003

**9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION**

Date of first registration: 5<sup>th</sup> November 2012

Date of last renewal: 4<sup>th</sup> November 2017

**10 DATE OF REVISION OF THE TEXT**

March 2019