

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **ECHINAFLU EFFERVESCENT TABLETS**

#### **1 NAME OF THE MEDICINAL PRODUCT**

ECHINAFLU effervescent tablets

ECHINACOLD effervescent tablets

#### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

One effervescent tablet contains 176 mg of dried pressed juice from fresh flowering Echinacea purpurea (L.) Moench herb (20-28:1).

This product contains 17.05 mmol (or 392 mg) sodium per tablet.

For full list of excipients, see section 6.1.

#### **3 PHARMACEUTICAL FORM**

Effervescent tablet

Round, flat, ivory-coloured effervescent tablets

#### **4 CLINICAL PARTICULARS**

##### **4.1 Therapeutic indications**

A traditional herbal medicinal product used to relieve the symptoms of the common cold and influenza type infections based on traditional use only.

##### **4.2 Posology and method of administration**

For oral administration

Adults, elderly and children over 12 years: the recommended dosage is 1 or 2 effervescent tablets daily, dissolved in a glass of water (about 200 ml). The dissolved tablets should be drunk immediately.

The effervescent tablet formulation is not intended for children below 12 years.

Start at first signs of common cold. Do not use the product for more than 10 days.

If symptoms worsen during the use of the product or persist for more than 10 days, a physician or a qualified healthcare practitioner should be consulted.

##### **4.3 Contraindications**

Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.

Because of its immunostimulating activity, Echinacea 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), diseases of the white blood cell system (e.g.: agranulocytosis, leukemias) and allergic diathesis (e.g.: urticaria, atopic dermatitis, asthma).

Children under 12 years of age.

#### **4.4 Special warnings and precautions for use**

Do not exceed the stated dose.

If the condition worsens or high fever occurs during the use of the product or if symptoms persist for more than 10 days, consult a doctor or qualified healthcare practitioner.

This formulation is not suitable for children under 12 years of age.

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

In patients for whom sodium intake is of medical concern (e.g. patients with congestive heart failure, renal failure, nephrotic syndrome), the sodium content of this product should be taken into account. Refer to Section 2, Qualitative and Quantitative Composition for sodium chloride content.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Not to be used concomitantly with immunosuppressant medications such as ciclosporin and methotrexate.

#### **4.6 Pregnancy and lactation**

In the absence of sufficient data the use in pregnancy and lactation is not recommended.

Limited data (several hundreds of exposed pregnancies) indicate no adverse effects of Echinacea on pregnancy or on the health of the foetus/newborn child. Data concerning the immune system of the newborn child are not available. To date, no other relevant epidemiological data are available. The potential risk for humans is unknown.

#### **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, Quincke edema, bronchospasm with obstruction, asthma and anaphylactic shock) may occur.

Echinacea can trigger allergic reactions in atopic patients.

Association with autoimmune diseases (encephalitis disseminata, erythema nodosum, immunothrombocytopenia, Evans Syndrome, Sjögren syndrome with renal tubular dysfunction) has been reported.

Leucopenia may occur in long-term use (more than 8 weeks).

The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.

#### **4.9 Overdose**

No case of overdose has been reported.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

No relevant pharmacodynamic data are available.

#### **5.2 Pharmacokinetic properties**

No relevant pharmacokinetic data are available.

#### **5.3 Preclinical safety data**

Echinacea purpurea showed no toxicity in single-dose toxicity, repeated-dose toxicity and genotoxicity studies.

Tests on reproductive toxicity and on carcinogenicity have not been performed.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Excipients of the herbal preparation:

Maltodextrin

Precipitated silicon dioxide

Citric acid monohydrate

Excipients of the tablet:

Ascorbic acid

Sodium hydrogen carbonate

Saccharin sodium

Sodium cyclamate

Citric acid anhydrous

Citric flavour Permaseal 84260-51.

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

Unopened

3 years.

After first opening the container

7 months.

## **6.4 Special precautions for storage**

Store in the original packaging.

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

Effervescent tablets are packed in polypropylene tubes with polyethylene closures filled with the drying agent silica gel.

One tube contains 20 effervescent tablets.

## **6.6 Special precautions for disposal**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Swiss Caps GmbH

Grassingerstraße 9

D-83043 Bad Aibling

Germany

## **8 MARKETING AUTHORISATION NUMBER(S)**

THR 18397/0004

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

16/06/2008

## **10 DATE OF REVISION OF THE TEXT**

8.6.2009