

# SUMMARY OF PRODUCT CHARACTERISTICS

## ECHINEEZE TABLETS

### 1 NAME OF THE MEDICINAL PRODUCT

EchinEeze Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 70mg of extract (as dry extract) from Echinacea purpurea root (equivalent to 460 – 530mg of Echinacea purpurea(L.) Moench root.) Extraction solvent: Ethanol 30% v/v. For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Tablet. Beige circular convex uncoated 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: take one tablet three times a day.

This product is not intended for children below 12 years.

Start at first signs of common cold.

Do not use the medicinal product for more than 10 days.

If symptoms worsen during the use of the product or persist for more than 10 days, a doctor 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), and diseases of the white blood cell system (e.g.: agranulocytosis, leukemias) 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 this product, or if symptoms persist for more than 10 days, a doctor or qualified healthcare practitioner should be consulted.

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

Keep out of the sight and reach of children

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

#### **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, erythemanodosum, 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 qualified healthcare practitioner should be consulted.

#### **4.9 Overdose**

No case of overdose has been reported.

#### **5.1 Pharmacodynamic properties**

No relevant pharmacokinetic data are available.

#### **5.2 Pharmacokinetic properties**

No relevant pharmacokinetic data are available

### **5.3 Preclinical safety data**

Tests on reproductive toxicity, genotoxicity and on carcinogenicity have not been performed with Echinacea purpurea root.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Herbal extract:

Maltodextrin Silica, colloidal, hydrated.

Tablet core:

Calcium hydrogen phosphate dehydrate, Cellulose, microcrystalline Silica, colloidal, hydrated. Crosscarmellose sodium Magnesium stearate

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

30 months

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

Store below 25°C

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

HDPE bottle with tamper evident closure and foam wad.

Printed card outer carton containing Patient Information Leaflet.

Pack sizes of 30, 60, 90, 120, and 180 tablets. Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

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

THR 16409/0002

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

31/07/2008

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

31/07/2008