

1.3 Product Information

1.3.1 SPC, Labelling and Package Leaflet

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ECHINAFLU soft capsules

ECHINACOLD soft capsules

LLOYDSPHARMACY Echinacea Cold Relief soft capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Soft capsule

Oval, green-coloured soft capsule

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 soft capsules daily.

The soft capsule formulation 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 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.

This product contains soya and should not be used by patients who are allergic to peanut or soya.

This product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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 soft capsule:

Refined soya-bean oil

Refined coconut oil

White beeswax

Rice starch

Fractionated palm kernel oil

Phospholipids from soya-beans

Succinylated gelatine

Glycerol

Non-crystallising sorbitol solution 70 %

Titanium dioxide E 171

Ferric (II,III) oxide E 172

Quinoline yellow E 104

Patent blue V E 131

Purified water

6.2. Incompatibilities

None known.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Do not store above 25 °C. Store in the original packaging.

6.5. Nature and contents of container

Soft capsules are packed in PVC/PVdC-aluminium blisters.

Pack sizes of 30, 45, 60 and 90 soft capsules.

6.6. Special precautions for disposal and other handling

No special requirements.

7. TRADITIONAL HERBAL REGISTRATION HOLDER

Swiss Caps GmbH
Grassingerstraße 9
D-83043 Bad Aibling
Germany

8. TRADITIONAL HERBAL REGISTRATION NUMBER

THR 18397/0003

9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION

16th June 2008

10. DATE OF REVISION OF THE TEXT

2nd July 2009