Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Echinace Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 127.0 mg of extract (as dry extract) from *Echinacea purpurea* radix (6-7:1) (equivalent to 762 mg - 889 mg of *Echinacea purpurea* (L.) Moench radix) (Purple coneflower root).

Extraction Solvent: Ethanol 30 %v/v.

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Film coated tablets.

Pale yellow, oval, biconvex tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used to relieve common cold and flu-like symptoms in adolescents and adults over 12 years of age, exclusively based on long-standing use.

4.2 Posology and method of administration

For oral short-term use only.

Swallow the tablets whole with water.

Adults, elderly and adolescents over 12 years: 1 tablet, three times a day, if required.

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

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 qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to Echinacea, to plants of the Asteraceae (Compositae) family or to any of the excipients listed in section 6.1.

Because of its immunostimulating activity, Echinacea must not be used in cases of progressive systemic diseases (tuberculosis, sarcoidosis), autoimmune diseases (e.g. collagenoses, multiple sclerosis), immunodeficiencies (e.g. HIV infection; AIDS), immunosuppression (e.g. onocological cytostatic therapy; history of organ or bone marrow transplant), diseases of the white blood cell system (e.g. agranulocytosis, leukaemias) and allergic diatheses (e.g.urticaria, atopic dermatitis, asthma).

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If symptoms persist, worsen or high fever occurs during the use of the product, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

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

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 interactions

Not to be used concomitantly with immunosuppressant medications.

4.6 Fertility, pregnancy and lactation

There are no or limited data from the use of Echinace 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, Sjögren syndrome with renal tubular dysfunction) has been reported.

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

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 the national reporting system:
HPRA Pharmacovigilance
Website: www.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(1)(a)(iii) of Directive 2001/83/EC as amended

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.3 Preclinical safety data

In vitro tests for detection of genetic mutation (Ames test) with *Echinacea purpurea* did not demonstrate genotoxic activity.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dry Extract
Maltodextrin
Colloidal Anhydrous Silica

Tablet core:
Calcium Hydrogen Phosphate Dihydrate
Microcrystalline Cellulose
Croscarmellose Sodium
Magnesium Stearate
Colloidal Anhydrous Silica

Film Coating:
Hypromellose
Purified Talc
Yellow Dispersion containing Hypromellose, Titanium Dioxide (E171) and Yellow Iron Oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in the original container.

6.5 Nature and contents of container

30, 60, 120 or 180 film coated tablets in a PVC/PVDC blister pack with aluminium foil.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR1725/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 4th July 2014
Date of last renewal: 3rd July 2019

10 DATE OF REVISION OF THE TEXT

April 2020