Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamberts Echinacea Cold & Flu Relief Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 105 mg dry extract, equivalent to 630-840 mg, of *Echinacea purpurea* (L.) Moench root (purple coneflower)
Extraction solvent: ethanol 75 % v/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
Clear-coated, beige, speckled, small oval 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.

4.2 Posology and method of administration

For oral short-term use only.

Adults, the elderly and adolescents over 12 years:
Take 1 tablet twice a day.
Swallow the tablets whole with water.
Do not chew the tablets.

Do not take this product for more than ten days.
If symptoms worsen or persist for more than ten days or if high fever occurs, consult a qualified healthcare professional e.g. a doctor or pharmacist.

Not recommended for use in children under 12 years (see section 4.4 special warnings and precautions for use)

4.3 Contraindications

Do not use in cases of known hypersensitivity to *Echinacea purpurea,* to plants of the Asteraceae (Compositae) family or to any of the excipients in section 6.1.

Because of its immune-modulatory 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).

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If symptoms worsen or high fever occurs during the use of the product or if symptoms persist for more than 10 days, consult a qualified healthcare professional e.g. a doctor or pharmacist.

There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult a qualified healthcare professional e.g. a doctor or pharmacist before using Echinacea.

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 interaction

Not to be used concomitantly with immunosuppressant medications.

4.6 Fertility, pregnancy and lactation

There are no or limited data from the use of Echinacea in pregnant women.
In the absence of sufficient data, the use in pregnancy and lactation is not recommended.
Studies on the effects on fertility have not been performed.

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 (skin rash, urticaria, Stevens-Johnson Syndrome, angioedema of the skin, Quincke edema, bronchospasm with obstruction, asthma and anaphylactic shock) have been reported.

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.

The alkylamides present in Lamberts Echinacea Cold & Flu Relief 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 a 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: 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 16 c (1) (a) (iii) of Directive 2001/83/EC as amended

5.2 Pharmacokinetic properties

Not required as per Article 16 c (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 extract did not demonstrate genotoxic activity.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal Preparation
Maltodextrin
Colloidal anhydrous silica

Tablet Core
Maltodextrin
Microcrystalline cellulose
Sodium croscarmellose
Stearic acid
Colloidal anhydrous silica
Magnesium stearate

Tablet Coating
Hypromellose
Glycerol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Tablets are packed into a PVC/PVDC blister strips in the following pack sizes: 30, 60 and 90 tablets and packed into a carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Lamberts Healthcare Limited,
1 Lamberts Road,
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8 REGISTRATION NUMBER(S)

TR2029/002/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 12th January 2018

10 DATE OF REVISION OF THE TEXT