Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Echinaforce Cold and Flu Oral Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

20 drops (one dose) is equivalent to 0.714 ml.
0.714 ml [approx. 0.646 g] of oral drops contains:
614 mg of tincture from fresh *Echinacea purpurea* (L.) Moench, herba (purple coneflower herb) (1:12-13) Extraction solvent: Ethanol 65% v/v
and
32 mg of tincture from fresh *Echinacea purpurea* (L.) Moench, radix (purple coneflower root) (1:11-12) Extraction solvent: Ethanol 65% v/v
1ml is equivalent to 28 drops.
Excipients with known effect:
One dose (20 drops) contains approx 0.464 ml (366 mg) of ethanol (alcohol).
For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution (oral drops)
Clear, olive-green coloured liquid

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

Posology

Adults, older people and adolescents over 12 years:
20 drops in a little water two to five times daily.

Start at first signs of common cold.

If symptoms persist, worsen or do not improve after 10 days use of this 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 (see 4.4 Special warnings and precautions for use).

Method of administration
For oral short-term use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance, to plants of the Asteraceae (Compositae) family or to any of the excipients listed in section 6.1.

Because of their immuno-modulatory activity, Echinacea extracts must not be used in cases of progressive systemic disorders (tuberculosis, sarcoidosis), autoimmune diseases (e.g. collagenoses, multiple sclerosis), immunodeficiencies (e.g. HIV infections,

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).

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

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

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

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

This medicine contains 366 mg of alcohol (ethanol) in each 20 drop dose, equivalent to 512 mg/ml. The amount in each 20 drop dose of this medicine is equivalent to less than 10 ml beer or 4 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

4.5 Interaction with other medicinal products and other forms of interaction

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole).

This product should not be used concomitantly with immunosuppressant medication.

4.6 Fertility, pregnancy and lactation

There are no or limited data from the use of Echinaforce oral drops 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.

This product contains alcohol. Overdose may result in alcohol intoxication (see section 4.4 for alcohol content).

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.

The alkylamides present in Echinaforce 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 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. Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.

In case of overdose symptoms according to ingested amount of ethanol can be expected (see section 4.4 for alcohol content).

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

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

Tests on reproductive toxicity have not been performed with *Echinacea purpurea* herb.

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

No mutagenic effects of Echinaforce drops were detected in Ames testing (with or without metabolic activation).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96% v/v
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years
Use within 4 months of opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottles (Ph. Eur. Type III) closed with a polyethylene/polyolefine two part dropper/dispenser with a polypropylene cap.

Pack sizes: 15 ml and 50 ml

Amber glass bottles (Ph. Eur. Type III) closed with a two part dropper/dispenser (LDPE) and a child-resistant closure (polypropylene/HDPE or HDPE/HDPE).

Pack sizes: 15 ml, 50 ml and 100 ml

Not all packs sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR2309/009/002

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 19th July 2013
Date of last renewal: 18th July 2018

10 DATE OF REVISION OF THE TEXT

October 2023