

SUMMARY OF PRODUCT CHARACTERISTICS

DUCHY HERBALS ECHINA-RELIEF TINCTURE

1 NAME OF THE MEDICINAL PRODUCT

Duchy Herbals Echina-Relief Tincture

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of oral liquid contains 1ml of tincture from dried Echinacea purpurea (L.) Moenchroot (1:3) (equivalent to 33 mg dried root). Extraction solvent: Ethanol 45% v/v. 1 ml of tincture contains approximately 360 mg ethanol (alcohol) equivalent to 9 ml beer or 4 ml wine. For full list of excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Oral liquid. Golden-brown.

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:
2.5 ml of tincture, in water, two or three times daily.

Not suitable for children under 12 years.

Start at first signs of common cold.

Do not use this 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.

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).

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.

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

This product contains approximately 45% v/v ethanol (alcohol), i.e. up to 900 mg per dose, equivalent to 23 ml beer or 10 ml wine per dose. Harmful for those suffering from alcoholism.

To be taken into account in high-risk groups such as patients with liver disease, or epilepsy.

4.5 Interaction with other medicinal products and other forms of interaction

Contains alcohol, and should therefore be avoided in patients taking other medications known to interact with alcohol (e.g. metronidazole). 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. This product contains alcohol (see Section 2).

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 qualified healthcare practitioner should be consulted.

4.9 Overdose

No case of overdose has been reported.

Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (18g in 50ml; 36g in 100ml: equivalent to one or two large glasses of wine, respectively) may result in intoxication and should be treated accordingly.

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

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (from tincture).

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

50ml or 100ml amber glass bottle, with 1 ml graduated glass pipette (subdivided at 0.5 ml), butyl-rubber bulb and HDPE plastic cap.

Plastic cap includes a tamper-evident collar that shears on first opening.

6.6 Special precautions for disposal

There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER

A. Nelson & Co. Limited
5 Endeavour Way
Wimbledon
London SW19 8UH

8 MARKETING AUTHORISATION NUMBER(S)

THR 01175/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/10/2008

10 DATE OF REVISION OF THE TEXT

10/10/2008