Duchy Herbals Echina-Relief Tincture

THR 01175/0004

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DUCHY HERBALS ECHINA-RELIEF TINCTURE

THR 01175/0004

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted A. Nelson & Co. Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Duchy Herbals Echina-Relief Tincture (Traditional Herbal Registration number: 01175/0004). This product is available without prescription and can be bought from pharmacies and other outlets.

Duchy Herbals Echina-Relief Tincture is used to relieve the symptoms of the common cold and influenza type infections, based on traditional use only. This medicine is an oral liquid containing the active ingredient dried *Echinacea purpurea* L. Moench root tincture.

This registration is based exclusively upon evidence of traditional use of *Echinacea purpurea* as a herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.

DUCHY HERBALS ECHINA-RELIEF TINCTURE

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Duchy Herbals Echina-Relief Tincture (Traditional Herbal Registration number: 01175/0004) to A. Nelson & Co. Limited on 10 October 2008. This product is on the general sales list (GSL).

The application was submitted under Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme.

This product consists of oral liquid containing 1 ml of tincture from dried *Echinacea purpurea* L. Moench root per 1 ml of liquid. Duchy Herbals Echina-Relief Tincture is used to relieve the symptoms of the common cold and influenza type infections. This THR is based exclusively on evidence of traditional use of *Echinacea purpurea*. The recommended dose is 2.5 ml of tincture, in water, two or three times daily.

The data supplied by the applicant demonstrate 30 years of traditional use of *Echinacea purpurea* in the European Community. A satisfactory review of the available safety data on *Echinacea purpurea* has also been provided.

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE

General information

Latin name: *Echinacea purpurea* (L.) Moench
Common name: Purple coneflower root
Other names: *Echinacea purpurea* radix
Family: Asteraceae / Compositae
Parts of plant used: Root (dried)

Description of the plant/herbal substance

Echinacea purpurea is a perennial plant of 60-100 cm in height (when cultivated it can reach up to 150 cm). The leaves, which have more or less serrated edges, are broad and oval, with an intense green upper side and are rather coarsely hirsute on both sides. The inflorescence is a single flower head terminating stem, comprised of approximately 20 purplish radial collar-like flowers.

Native to North America, where it has been used in traditional medicine for centuries, *Echinacea purpurea* grows on plains and sandy riversides. The plant is cultivated as a medicinal plant in numerous Central European countries and it has become naturalized in many places in Europe.

Manufacture

The herbal substance used in this product is sourced from either The Netherlands or Germany. The plant material is collected in accordance with Good Agricultural and Collection Practice (GACP) guidelines, without the use of ethylene oxide.

Control of Herbal Substance

Herbal substance obtained from growers is quarantined prior to quality control and release. Release is dependent on receipt of a satisfactory Certificate of Analysis from the grower.

An appropriate specification based on the Ph Eur monograph for *Echinacea purpurea* root is used. Tests carried out are stated to be in line with Ph Eur methods, therefore, additional validation is not required. The specification is supported by the batch data provided.

Container Closure System

A suitable container is used to store the herbal substance.

Stability

Stability data for the herbal substance are not available. The herbal substance is not stored prior to use in the manufacture of the the herbal preparation but is essentially ordered for immediate use in manufacture. Should delays in delivery of plant materials occur, plant material will be re-tested prior to use in manufacture of the herbal preparation.

HERBAL PREPARATION

General information

Latin name: Echinacea purpurea radix tincture
Part of plant used: Dried root
Drug to extract ratio: 1:3
Extractant: Ethanol 45% v/v
General Properties: Golden brown colour with a slightly spicy herbal odour

Manufacture
A satisfactory description and flow-chart of the manufacturing method has been provided.

An up to date GMP certificate has been provided for the manufacturing site.

Control of Materials
The materials used in the preparation of the herbal tincture are the herbal substance and the extraction solvent. The herbal substance is extracted with ethanol 45%. The ethanol complies with the Ph Eur and suitable certificates of analysis have been provided.

The water used is purified and complies with the Ph. Eur., a suitable specification is provided.

Controls of Critical Steps and Intermediates
No critical steps have been identified.

Process Validation and/ or Evaluation
Manufacture of the tincture is a standard maceration process as described in Ph Eur. The Ph Eur describes tinctures prepared by maceration or percolation using ethanol of a suitable concentration, or by dissolving a soft or dry extract (prepared using the same strength of ethanol) in ethanol. Nelsons have considerable experience with manufacture of herbal and homoeopathic tinctures.

Characterisation
Suitable tests are performed to elucidate the characteristics of the herbal preparation.

Control of Herbal Preparation
Specification
A satisfactory specification, with appropriate tests and limits has been provided for the herbal preparation

Analytical Procedures/ Validation of Analytical Procedures
Analytical methods are either those of the Ph Eur or have been fully validated.

Batch Analyses
Batch analysis data are provided and these comply with the proposed specification.

Justification of Specification
The proposed specification has been justified satisfactorily.

Reference Standards or Materials
Reference materials used are confirmed to be in accordance with Ph Eur standards.

Container Closure System
The herbal preparation is stored in a suitable container closure system. A description of the container closure system is provided. The stability data provided show no incompatibilities between the herbal preparation and the container.

Stability
No information has been provided. As the tincture is not stored prior to filling into the final container, this is satisfactory.

HERBAL PRODUCT

Description and Composition of the Herbal Product

The product is an oral liquid consisting of the *Echinacea purpurea* root tincture without any excipients

The herbal preparation is an ethanolic extract containing 45% ethanol by volume. The high level of alcohol is considered to afford adequate antimicrobial preservation to the herbal preparation.
There are no overages in this product.

Manufacture

Manufacture

Manufacture simply involves filling the bulk tincture into final bottles.

Control of Excipients

Not applicable.

Control of Herbal Product

Specification

The finished product specifications at release and end of shelf life are detailed and the tests and limits applied were found to be satisfactory for a product of this nature.

Analytical Procedures

Satisfactory details have been provided on all analytical procedures and these analytical procedures are valid.

Batch Analyses

Satisfactory batch data have been provided to support the specifications.

Justification of Specification

The proposed release and shelf-life specifications have, in general been adequately justified with respect to the parameters controlled and the limits applied.

Reference Standards or Materials

Reference materials used are confirmed to be in accordance with Ph Eur standards.

Container Closure System

The finished product is presented in 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.

Stability

Stability studies have been conducted under ICH conditions (long term, accelerated). The results support the proposed shelf life of 24 months with the storage precaution ‘Do not store above 25°C’.

Product literature

The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product are pharmaceutically satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and

written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY

This product is satisfactory and a Traditional Herbal Registration can be granted.

NON-CLINICAL ASSESSMENT

NONCLINICAL ASPECTS

The Expert Safety Report submitted by the applicant lists relevant references to published work studying the toxicology of *Echinacea purpurea*.

NONCLINCIAL OVERVIEW

The applicant has submitted an adequate literature review with this application. An Expert Report on Safety was provided, which included reviews of some non-clinical data. The author of the Expert Safety Report has expertise in herbal medicines.

The overview submitted in support of this application is satisfactory.

Due to a shortage of published data on *Echinacea purpurea*, it is not possible to assess if the safety package for the phytochemical constituents of *Echinacea purpurea* is acceptable to the standards of today's GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and thus the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/05.

Data in the literature for genotoxic and carcinogenic potential of the product is deficient as basic genotoxicity tests have not been conducted. The company have provided their assurance that they will address this lack of data before renewal of their licence.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC for this product is satisfactory from a preclinical point of view.

ENVIRONMENTAL RISK ASSESSMENT

An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

CONCLUSION

The information supplied demonstrating traditional use of *Echinacea purpurea* is acceptable. An adequate literature review of *Echinacea purpurea* has been carried out by the applicant and no new non-clinical data was submitted for assessment with this application. Granting of a THR is acceptable.

CLINICAL ASSESSMENT

LEGAL STATUS
Echinacea purpurea is on the General Sales List for internal use.

PROPOSED INDICATION
The applicant has proposed the following indication, which is acceptable:

"A traditional herbal medicinal product used to relieve the symptoms of the common cold and influenza type infections based on traditional use only."

EVIDENCE OF LONG-STANDING USE
Article 16 c 1 (c) requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within an EU Member State.

The applicant has provided information that satisfies this requirement.

SAFETY REVIEW
Article 16 c 1 (D) requires the applicant to provide a bibliography of safety data together with a Safety Expert Report.

A safety review has been provided as well as an expert report written by a medical herbalist. His CV is included.

The clinical review of safety submitted in the dossier outlined adverse events from controlled and uncontrolled studies relevant to the safety of *Echinacea purpurea*.

Assessor's comment
A satisfactory and comprehensive review of the literature has been provided. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. The applicant has, therefore, provided assurance that appropriate genotoxicity testing will be performed prior to renewal of this registration.

PRODUCT LITERATURE
The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product are medically satisfactory.

The package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

LEGAL STATUS
Echinacea purpurea is on the General Sales List for internal use.

DISCUSSION

The data supplied by the Applicant are sufficient to demonstrate 30 years of traditional use, including at least 15 years within an EU Member State, for required for registration under the Traditional Herbal Medicines Product Directive.

A satisfactory review of the available safety data relating to *Echinacea purpurea* has been provided, together with an expert report supporting the registration of the product. All product literature is satisfactory.

RECOMMENDATIONS

A Traditional Herbal Registration may be granted.

OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY AND SAFETY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products (THMP).

The Applicant has provided a bibliographic review which shows ample evidence of the use of *Echinacea purpurea* for more than 30 years and within the EU for a period exceeding 15 years.

A satisfactory review of the safety data has been provided.

The SPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.

DUCHY HERBALS ECHINA-RELIEF TINCTURE

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the Traditional Herbal Registration application on 3 December 2006
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 20 March 2007
3	Following assessment of the application the MHRA requested further information relating to the dossier on 16 July 2007
4	The applicant responded to the MHRA's requests, providing further information on the dossier on 19 March 2008
5	Following assessment of the response the MHRA requested further information relating to the dossier on 2 April 2008
6	The applicant responded to the MHRA's requests, providing further information on the dossier on 14 April 2008
7	Following assessment of the response the MHRA requested further information relating to the dossier on 14 April 2008
8	The applicant responded to the MHRA's requests, providing further information on the dossier on 16 June 2008
9	Following assessment of the response the MHRA requested further information relating to the dossier on 16 June 2008
10	The applicant responded to the MHRA's requests, providing further information on the dossier on 10 July 2008
11	Following assessment of the response the MHRA requested further information relating to the dossier on 10 July 2008
12	The applicant responded to the MHRA's requests, providing further information on the dossier on 4 August
13	Following assessment of the response the MHRA requested further information relating to the dossier on 4 August
14	The applicant responded to the MHRA's requests, providing further information on the dossier on 10 October
15	A THR was granted on 10 October

SUMMARY OF PRODUCT CHARACTERISTICS

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.) Moench root (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

PATIENT INFORMATION LEAFLET

PRODUCT DESCRIPTION:

Echina-Relief Tincture is a golden brown liquid.

Each 1ml of oral liquid contains 1ml of tincture from dried ***Echinacea purpurea*** (L.) root (1:3) (equivalent to 33mg dried root).

Extraction solvent: Ethanol 45% v/v.

There are no other ingredients in this product.

This product is available in packs of 50ml and 100ml.

The Traditional Herbal Registration Holder and Manufacturer of this product is:

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

THR 01175/0004
Leaflet prepared September 2008

Further information on Echinacea:

Echinacea, which has the common name Purple Coneflower, has a long standing tradition of use as a herbal remedy. There are several different species of Echinacea, and this product contains **Echinacea purpurea**, which is the species most widely used in herbal medicine.

Echinacea is believed to have been used first as a herbal medicine by Native American peoples and its use by herbal practitioners is documented from the late 19th century onwards.

What you can do to help ease your cold:

Everybody catches a cold from time to time.
Try to keep warm, drink plenty of fluids and get as much rest as you can.

DUCHY HERBALS

Echina-Relief Tincture

Echinacea purpurea **root**

A traditional herbal medicinal product used to relieve symptoms of the common cold & influenza type infections based on traditional use only.

For oral administration

Please read this leaflet carefully before taking this product. It contains important information, including what this product does, what you need to know before you take it, how you should take it and how you should keep it.

PLEASE KEEP THIS LEAFLET, YOU MAY NEED TO READ IT AGAIN.

Ask your doctor, pharmacist or healthcare practitioner if you feel you need further information and advice about taking this product.

WHAT THIS PRODUCT IS AND WHAT IT IS USED FOR:

Echina-Relief Tincture is a traditional herbal medicinal product used to relieve the symptoms of the common cold and influenza type infections. This usage is based on traditional use only.

This product contains ***Echinacea purpurea*** root tincture, which is the active ingredient. Each 1ml of oral liquid contains 1ml of tincture from dried ***Echinacea purpurea*** (L.) root (1:3) (equivalent to 33mg dried root).

Extraction solvent: Ethanol 45% v/v.

BEFORE TAKING THIS PRODUCT:

Do not take this product if you:

- are allergic to any of the ingredients or to plants of the Asteraceae (Compositae) family such as daisies, marigolds or artichokes
- have a tendency to allergies such as hives, allergic eczema or asthma
- are pregnant or breastfeeding
- suffer from the infection tuberculosis
- suffer from connective tissue disease with formation of clumps of cells (sarcoidosis), mainly occurring in the lymph nodes, lungs and liver
- suffer from autoimmune diseases such as inflammation of the connective tissue (collagenoses) or multiple sclerosis
- suffer from conditions which decrease your resistance to infection (e.g. HIV infection or AIDS) or
- are on therapy to reduce your natural response to infection (immunosuppression e.g. chemotherapy or radiotherapy for cancer; history of organ or bone marrow transplant)
- suffer from blood disorders involving the white blood cell system such as low white blood cell count due to bone marrow disorders (agranulocytosis) or blood cell cancer (leukemias)
- are under 12 years of age

Take special care with Echina-Relief Tincture.

- you should avoid alcohol
- do not exceed the stated dose

You must contact a doctor or qualified healthcare practitioner if

- you have a high fever or your condition worsens
- symptoms persist for more than 10 days
- adverse effects not mentioned in the patient information leaflet occur

If you are prone to allergies there is a risk of developing serious allergic reactions to Echinacea (e.g. anaphylactic reactions).

Patients should be aware that intake of products containing Echinacea species may trigger autoimmune diseases.

This product contains 45% v/v ethanol (alcohol). Each 1ml of tincture contains approximately 360mg of alcohol, equivalent to 9ml of beer or 3.75ml of wine. Harmful for people suffering from alcoholism.

This formulation is not suitable for children under 12 years of age.

Taking other medicines

Echina-Relief must not be used together with immunosuppressant medications such as ciclosporin and methotrexate.

This product contains alcohol and should not be used together with medicines known to interact with alcohol, for example metronidazole.

Always remember to tell your doctor about any medicines you are taking including those obtained without prescription.

Pregnancy and breastfeeding

Do not take this product if you are pregnant or breastfeeding.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. This product contains alcohol (see above).

HOW TO TAKE THIS PRODUCT:

You should speak to your doctor, pharmacist or healthcare practitioner if you are not sure if this product is suitable for you.

Check that the bottle seal is intact before first use.
This pack contains a glass dropper inside the bottle. You can use this dropper to measure out the product into a glass of water

Start taking this product at the first signs of a common cold.

Adults, elderly, children over 12 years:

Take 2.5ml, in a glass of water, two or three times daily.

Not suitable for children under the age of 12 years.

Do not use this product for more than 10 days.

Do not exceed the stated dose.

If you take too much of this product (overdose)

Overdose of this product may result in alcohol intoxication and should be treated accordingly. See section "Take special care with Echina-Relief Tincture".

Speak to your doctor or pharmacist and take this leaflet with you.

If you forget to take this product

Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

POSSIBLE SIDE EFFECTS:

Like all medicines Echina-Relief Tincture may cause side effects, although not everybody gets them. Stop taking Echina-Relief and check with your doctor, pharmacist or qualified healthcare practitioner immediately if any of the following side effects occur:

Allergic (hypersensitive) reactions such as:

- rash
- hives
- inflammatory disorder of the skin (Stevens-Johnson-Syndrome)
- swelling of the skin due to fluid
- swelling of the facial area (Quincke's oedema)
- shrinking of the airways in the lungs with obstruction (bronchospasm)
- asthma and life-threatening allergic reactions (anaphylactic shock)

Echinacea can trigger allergic reactions in patients who have a tendency to develop allergic conditions.

Association with autoimmune diseases has been reported such as:

- inflammation of the brain and spinal cord (disseminated encephalitis)
- painful lumps on the shins (erythema nodosum)
- low blood platelet count (immunothrombocytopenia)
- destruction of blood cells by antibodies (Evans Syndrome)
- dryness in the mouth and eyes with renal tubular dysfunction (Sjögren Syndrome)

A decrease in the number of white blood cells (leucopenia) may occur in long-term use (more than 8 weeks). The frequency is not known.

If the condition worsens, or if symptoms persist for more than 10 days, or if side effects not mentioned in this leaflet occur, consult your doctor or pharmacist.

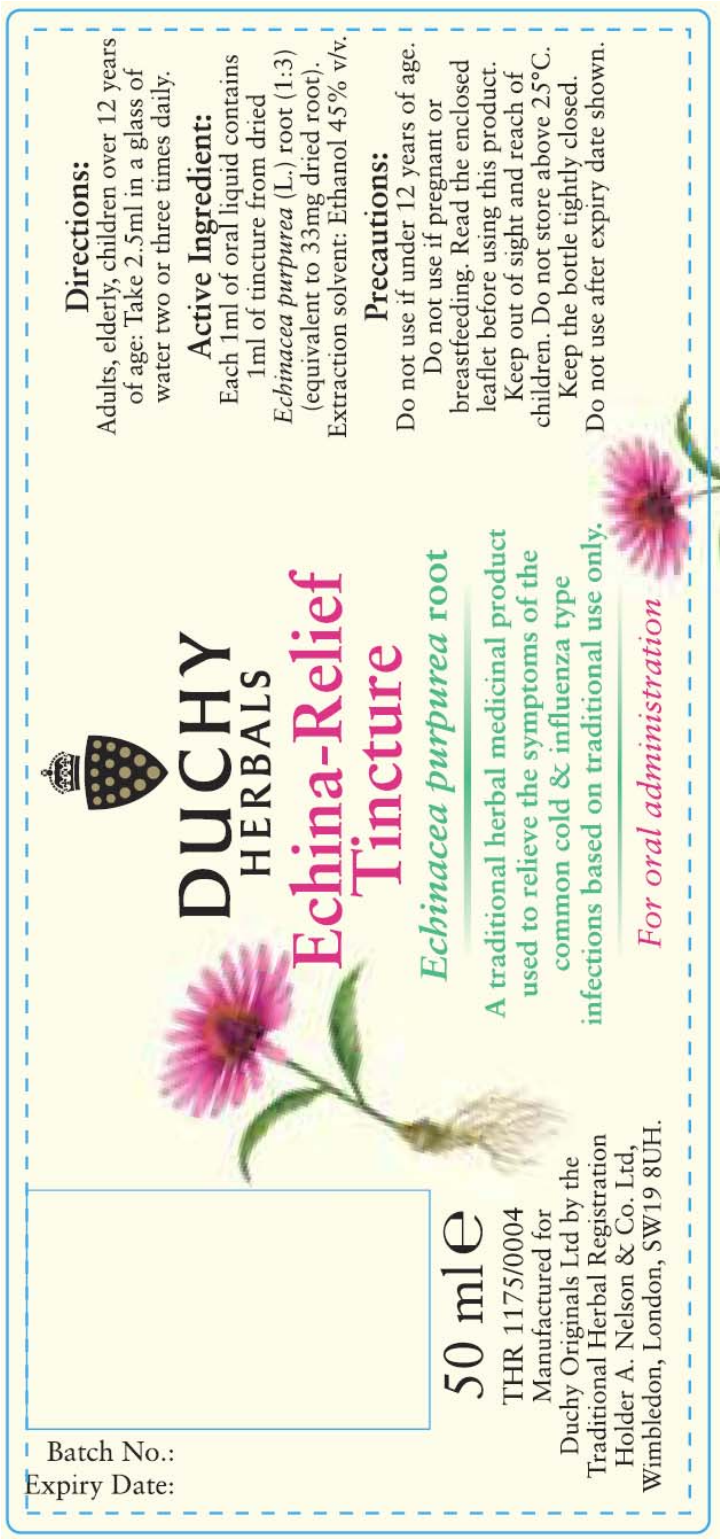
STORING THIS PRODUCT:

Keep all medicines out of the reach and sight of children. Once opened, store in a cool dry place. Do not store above 25°C. Keep the bottle tightly closed. Do not use after the expiry date shown on the carton and bottle.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

LABELLING

Label:



Carton:


DUCHY HERBALS
Echina-Relief Tincture
Echina-Relief Tincture
Echina-Relief Tincture is a traditional herbal medicinal product used to relieve the symptoms of the common cold and influenza type infections, based on traditional use only.
Echinacea, which has the common name Purple Coneflower, has a long standing tradition of use as a herbal remedy. There are several different species of Echinacea, and this product contains Echinacea purpurea, which is the species most widely used in herbal medicine.
Echinacea is believed to have been used first as a herbal medicine by Native American people, and its use by herbal practitioners is documented from the late 19th century onwards.
THR 1175/0004
Manufactured for Duchy Originals Ltd by the Traditional Herbal Registration Holder
A. Nelson & Co. Ltd,
Wimbledon, London,
SW19 8UH.
Batch No.:
Expiry Date:
Echina-Relief Tincture
Active Ingredient:
Each 1ml of oral liquid contains 1ml of tincture from dried Echinacea purpurea (L.) root (1:3) (equivalent to 33mg dried root).
Extraction solvent: Ethanol 45% v/v.
Directions:
Please read the enclosed leaflet carefully before taking this product. Check that the bottle seal is intact before first use.
For oral administration
Adults, elderly, children over 12 years of age:
Take 2.5ml in a glass of water two or three times daily.
Do not exceed the stated dose.
DUCHY HERBALS
Echina-Relief Tincture
Echinacea purpurea root
A traditional herbal medicinal product used to relieve symptoms of the common cold & influenza type infections based on traditional use only.
oral liquid
50 ml e
Echina-Relief Tincture
Precautions:
Do not take if:
• you are under 12 years of age
• you are pregnant or breastfeeding
• you are allergic to any of the ingredients
Talk to your doctor or pharmacist before taking this product if:
• you have a serious infection or high fever
• you suffer from asthma or atopic dermatitis
• you suffer from epilepsy or liver disease
If your symptoms worsen, persist for more than 10 days or if side effects not mentioned in the patient information leaflet occur, contact your doctor, pharmacist or healthcare practitioner for further advice.
Please read the enclosed leaflet for further information.
This product also contains alcohol. Harmful for people suffering from alcoholism.
Keep out of sight and reach of children.
Once opened, store in a cool dry place.
Do not store above 25°C.
Do not use after the expiry date on the carton and bottle.