

Echinaboost film-coated tablets

Herbal Classics Echinacea Cold Relief film-coated tablets

THR 15525/0009

UKPAR

TABLE OF CONTENTS

Lay summary	Page 2
Scientific discussion	Page 3
Steps taken for assessment	Page 10
Summary of product characteristics	Page 11
Product information leaflet	Page 15
Labelling	Page 20

ECHINABOOST FILM-COATED TABLETS

HERBAL CLASSICS ECHINACEA COLD RELIEF FILM-COATED TABLETS

THR 15525/0009

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Pharbio Medical International AB a Traditional Herbal Registration certificate for the traditional herbal medicinal products Echinaboost film-coated tablets and Herbal Classics Echinacea Cold Relief film-coated tablets. These products are identical to each other apart from the difference in product name and share the same Traditional Herbal Registration number: THR 15525/0009. They will collectively be referred to as Echinacea film-coated tablets for the remainder of this report. This product is available without prescription and can be bought from pharmacies and other outlets.

Echinacea film-coated tablets is a traditional herbal medicinal product used to relieve the symptoms of common cold and influenza type infections. The active ingredient in Echinacea film-coated tablets come from the roots of the Echinacea plant (*Echinacea purpurea* L.).

This registration is based exclusively upon evidence of the use of Echinacea root as a traditional 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.

ECHINABOOST FILM-COATED TABLETS
HERBAL CLASSICS ECHINACEA COLD RELIEF FILM-COATED TABLETS

THR 15525/0009

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction	Page 4
Pharmaceutical assessment	Page 5
Preclinical assessment	Page 7
Clinical assessment	Page 8
Overall conclusions and risk assessment	Page 9

INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Echinacea film-coated tablets (THR 15525/0009) to Pharbio Medical International AB on 19 November 2010. This product is on the general sales list (GSL).

A product licence (PL 11357/0004) was granted to Medic Herb UK Ltd for this product on 25 March 1993. Following a change of ownership on 18 April 2007 the product licence was transferred to Pharbio Medical International AB under product licence number PL 15525/0004. Confirmation is given that PL 15525/0004 will be cancelled after the THR is granted.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a marketing authorisation (product licence) to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A as no changes have been made to the formulation of the product. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: ECHINACEA ROOT

Scientific name of the plant: *Echinacea purpurea* L.
Family: Asteraceae
Synonyms of the herbal substance: Echinacea
Parts of the plant used: root

The herbal substance complies with the Ph. Eur. monograph, it is, therefore, acceptable.

HERBAL PREPARATION: ECHINACEA ROOT DRY EXTRACT

Herbal preparation: Echinacea root dry extract
Parts of the plant used: root
Extraction solvent: ethanol 45 % v/v

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

HERBAL PRODUCT: ECHINACEA FILM-COATED TABLETS TABLETS

Description and Composition of the Herbal Product

Echinacea film-coated tablets are round, biconvex, brown-grey speckled, film-coated tablets. The tablets contain the excipients cellulose, colloidal anhydrous silica dioxide, lactose monohydrate, glucose liquiritae radix extract, menthol racemic, hydrated dextrate, sorbitol, talc, microcrystalline cellulose, colloidal silica dioxide, magnesium stearate, eucalyptus oil, anise oil, fennel oil, clove oil, hypromellose, macrogol and water. The formulation is identical to that of the already licensed product. It is, therefore, acceptable.

Manufacture

The manufacturing process is in line with that of the already licensed product and is satisfactory.

Finished Product Specification

The finished product specification is in line with that of the already licensed product and is satisfactory.

Container Closure System

The tablets are stored in foil strip blister packs packed in a cardboard carton. Each cardboard carton of 40, 60 or 80 tablets consists of 2x20, 3x20 or 4x20 foil strip blister packs, respectively. This type of packaging has been used to store the already licensed product and is satisfactory.

Stability

The product shelf-life of 2 years was applied to the already licensed product and is appropriate when the storage precautions 'do not store above 25°C' is applied.

Summary of Product Characteristics, label and Patient Information Leaflet

All product literature is in line with that of the already licensed product, with some details amended in line with other valerian-containing products registered under the THR scheme.

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

The grant of a Traditional Herbal Registration is acceptable.

NON-CLINICAL ASSESSMENT

INTRODUCTION

No new preclinical data have been supplied with this application and none is required for an application of this type.

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the THR.

PRODUCT LITERATURE

All product literature is satisfactory from a preclinical point of view.

ASSESSOR'S OVERALL CONCLUSIONS

It is recommended that a Traditional Herbal Registration can be granted.

CLINICAL ASSESSMENT

INTRODUCTION

The clinical particulars for Echinacea film-coated tablets are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE

All product literature is medically satisfactory.

ASSESSOR'S OVERALL CONCLUSIONS

It is recommended that a Traditional Herbal Registration can be granted.

OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY

Echinacea film-coated tablets is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY

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

SAFETY

No new or unexpected safety concerns arose from this application.

RISK ASSESSMENT

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

ECHINABOOST FILM-COATED TABLETS
HERBAL CLASSICS ECHINACEA COLD RELIEF FILM-COATED TABLETS

THR 15525/0009

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Traditional Herbal Registration application on 26 April 2010
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 27 May 2010
- 3 Following assessment of the application the MHRA requested further information relating to the dossier on 22 July 2010
- 4 The applicant responded to the MHRA's requests, providing further information on the dossier on 16 November 2010
- 5 A THR was granted on 19 November 2010

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Echinaboost film-coated tablets

Herbal Classics Echinacea Cold Relief film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains 40 mg of extract (as dry extract) (6.5:1) equivalent to 260 mg

Echinacea purpurea root (*Echinacea purpurea* L. Moench)

Extraction solvent: Ethanol 45% V/V.

Excipient(s): One tablet contains lactose monohydrate 7 mg, glucose (dextrose) 261 mg and sorbitol 110 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Round, biconvex, brown-grey speckled tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For oral short term use only.

The tablets can be chewed or swallowed whole.

Adults, elderly and children over 12 years:

2 to 3 tablets 3 times a day.

Maximum: 9 tablets per day.

This tablet formulation is not intended for children below 12 years.

Start at first signs of common cold.

Echinaboost should not be used for longer periods than 10 days.

If symptoms worsen during the use of the product or persist for more than 10 days, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance or to other plants of the Asteraceae (Compositae) family or to any of the excipients.

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), diseases of the white blood cell system (e.g.: agranulocytosis, leukemias) and allergic diathesis (e.g.: urticaria, atopic dermatitis, asthma).

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 doctor or qualified healthcare practitioner should be consulted.

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

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

Since the tablet contains lactose monohydrate, glucose and sorbitol (see section 6.1) patients with rare hereditary problems of galactose intolerance, fructose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.8 Undesirable effects

Hypersensitivity reactions (rash, urticaria, Stevens-Johnson Syndrome, angioedema of the skin, Quincke oedema, bronchospasm with obstruction, asthma and anaphylactic shock) may occur (see section 4.4). 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 a pharmacist should be consulted.

4.9 Overdose

No case of overdose has been reported. However, due to the sorbitol content, overdoses may result in diahorrea.

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

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Extract excipients.

Cellulose

Colloidal anhydrous silica dioxide

Lactose monohydrate

Glucose (in liquiritae extract)

Tablet core

Liquiritae radix extract

Menthol racemic

Hydrated dextrate

Sorbitol

Talc

Microcrystalline cellulose

Colloidal silica dioxide

Magnesium Stearate
Eucalyptus Oil
Anise Oil
Fennel Oil
Clove Oil

Tablet coating.
Hypromellose
Macrogol
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Each cardboard carton of 40 tablets consists of 2 x 20 foil strip blister packs

Each cardboard carton of 60 tablets consists of 3 x 20 foil strip blister packs

Each cardboard carton of 80 tablets consists of 4 x 20 foil strip blister packs

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

PHARBIO MEDICAL INTERNATIONAL AB

BOX 715

SE-194 27 UPPLANDS VÄSBY

SWEDEN

8 MARKETING AUTHORISATION NUMBER(S)

THR 15525/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/11/2010

10 DATE OF REVISION OF THE TEXT

19/11/2010

PRODUCT INFORMATION LEAFLET

**Package leaflet:
Information for the user**

Echinaboost film-coated tablets

Echinacea purpurea root extract 40 mg

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Echinaboost carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 10 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or qualified healthcare practitioner.

In this leaflet:

1. What Echinaboost is and what it is used for
2. Before you take Echinaboost
3. How to take Echinaboost
4. Possible side effects
5. How to store Echinaboost
6. Further information



1. What Echinaboost is and what it is used for

Echinaboost is a traditional herbal medicinal product used to **relieve the symptoms of common cold and influenza type infections**, based on traditional use only.

The tablets contain an extract of Echinacea purpurea root.

For full details see section 6.

2. Before you take Echinaboost

This product is not suitable for Children under 12 years of age.

Do not take Echinaboost if you are allergic to:

- Echinacea or products from the same plant family (Asteraceae/Compositae) such as daisies, marigolds or artichokes.
- Any of the other ingredients of Echinaboost (listed in Section 6 below).

Or if:

- You have **frequent allergic reactions** such as hives, eczema or asthma.
- You have **tuberculosis** infection.
- You have a **connective tissue disease** with formation of clumps of cells (sarcoidosis) mainly occurring in the lymph nodes, lungs and liver.

- You have auto-immune diseases such as **inflammation of the connective tissue** (collagenosis) or **multiple sclerosis**.
- You have conditions which decrease your natural response to infection such as **HIV** infection or **AIDS**.
- You are on any treatment which lowers your natural response to infection (immunosuppression) such as **chemotherapy** or **radiotherapy for cancer**; or have had **organ or bone marrow transplantation**.
- You have any **blood disorders** involving the white blood cell system such as low white cell count due to **bone marrow disorders** (agranulocytosis) or **blood cell cancer** (leukaemia).
- You are already taking other medicines which lower your immune system (immunosuppressants) such as ciclosporin or methotrexate.

This product contains lactose monohydrate, glucose and sorbitol. If you have been told by your doctor that you have an **intolerance** to some sugars **do not take** Echinaboost.

Take special care with Echinaboost

- If there is a family history of allergic reactions.
- Because echinacea can trigger auto-immune diseases.

Taking other medicines

Please tell your doctor or qualified healthcare practitioner if you are taking any other medicines.

Pregnancy and breast-feeding

Do not take Echinaboost if you are pregnant or breast-feeding, because there is no evidence that it is safe to do so. Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take Echinaboost

For oral short term use only.

Take Echinaboost as advised in this leaflet. You should check with your doctor or qualified healthcare practitioner if you are not sure.

Do not exceed the stated dose.

Chew the tablet or swallow it whole with water.

Adults, elderly and children over 12 years

Take 2 to 3 tablets 3 times a day. Do not take more than 9 tablets a day.

This tablet formulation is not intended for children under 12 years.

Start your treatment at the first signs of common cold.

Do not use for more than 10 days.

Contact your doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 10 days.

FM400802GB2

22400802

If you take more Echinaboost than you should

If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you. Because of the sugar content taking too much Echinaboost may cause diarrhoea.

If you forget to take Echinaboost

Continue to take your usual dose at the usual time. It does not matter if you have missed a dose. Do not take a double dose to make up for forgotten tablets.

If you have any further questions on the use of this product, ask your doctor or a qualified healthcare practitioner.

4. Possible side effects

Like all medicines, Echinaboost can cause side effects, although not everybody gets them.

The frequency of the side effects is not known.

The possible side effects include:

- Skin rash.
- Red, itchy skin (hives).
- Swelling of the skin due to fluid (angioedema).
- Swelling of the face (Quincke's oedema).
- Blistering of the skin and mucous membranes (Stevens-Johnson Syndrome).
- Difficulty in breathing (bronchospasm with obstruction).
- Asthma and life threatening reactions (anaphylactic shock).

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

Stop taking Echinacea Cold Relief immediately if you experience any allergic reaction.

Association with diseases of the immune system (autoimmune diseases) have been reported with the use of echinacea such as:

- Inflammation of the brain and spinal chord (disseminated encephalitis).
- Painful lumps on the shins (erythema nodosum).
- Low blood platelet count (immuno-thrombocytopenia).
- Destruction of blood cells by antibodies (Evans Syndrome).
- Dryness in the mouth and eyes with kidney tubular dysfunction (Sjögren syndrome).

A decrease in the number of white blood cells (leucopenia) may occur in long term use (more than 8 weeks).

If you are concerned about any side effect, if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or qualified healthcare practitioner. You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.yellowcard.gov.uk. Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call freephone 0808 100 3352 (available 10 am–2 pm Monday–Friday).

5. How to store Echinaboost

Do not store above 25°C.

Keep out of the reach and sight of children.

Do not use Echinaboost after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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

6. Further information

What Echinaboost contains

- Each film-coated tablet contains 40 mg of extract (as dry extract) (6.5:1) equivalent to 260 mg of Echinacea purpurea root (*Echinacea purpurea* L. Moench).

Extraction solvent: Ethanol 45% V/V.

- The **other ingredients** are liquorice extract, menthol, hydrated dextrate, sorbitol, talc, microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, eucalyptus oil, anise oil, fennel oil, clove oil, 7 mg lactose monohydrate, cellulose, colloidal anhydrous silica dioxide.

What Echinaboost looks like and contents of the pack

The film-coated tablets are brown/grey-speckled and round.

Pack sizes: 40, 60, 80 tablets in blisters.

Not all pack sizes may be marketed.

Traditional Herbal Registration Holder

Pharbio Medical International AB,
Box 715, SE-194 27 Upplands Väsby,
Sweden.

Telephone: +46 8 590 963 00

E-mail: regulatory@cederth.com

Manufacturer

Cederth International Production
Paramedical A/S,
Vassingerødvej 3-7, DK-3540 Lyngø,
Denmark.

This leaflet was last approved in November 2010



CERTIFICATION MARK

**Package leaflet:
Information for the user**

**Herbal Classics
Echinacea Cold Relief
film-coated tablets**

Echinacea purpurea root extract 40 mg

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Echinacea Cold Relief carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 10 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or qualified healthcare practitioner.

In this leaflet:

1. What Echinacea Cold Relief is and what it is used for
2. Before you take Echinacea Cold Relief
3. How to take Echinacea Cold Relief
4. Possible side effects
5. How to store Echinacea Cold Relief
6. Further information



1. What Echinacea Cold Relief is and what it is used for

Echinacea Cold Relief is a traditional herbal medicinal product used to **relieve the symptoms of common cold and influenza type infections**, based on traditional use only.

The tablets contain an extract of Echinacea purpurea root.

For full details see section 6.

2. Before you take Echinacea Cold Relief

This product is not suitable for Children under 12 years of age.

Do not take Echinacea Cold Relief if you are allergic to:

- Echinacea or products from the same plant family (Asteraceae/Compositae) such as daisies, marigolds or artichokes.
- Any of the other ingredients of Echinacea Cold Relief (listed in Section 6 below).

Or if:

- You have **frequent allergic reactions** such as hives, eczema or asthma.
- You have **tuberculosis** infection.
- You have a **connective tissue disease** with formation of clumps of cells (sarcoidosis) mainly occurring in the lymph nodes, lungs and liver.

- You have auto-immune diseases such as **inflammation of the connective tissue** (collagenosis) or **multiple sclerosis**.
- You have conditions which decrease your natural response to infection such as **HIV** infection or **AIDS**.
- You are on any treatment which lowers your natural response to infection (immunosuppression) such as **chemotherapy** or **radiotherapy for cancer**; or have had **organ or bone marrow transplantation**.
- You have any **blood disorders** involving the white blood cell system such as low white cell count due to **bone marrow disorders** (agranulocytosis) or **blood cell cancer** (leukaemia).
- You are already taking other medicines which lower your immune system (immunosuppressants) such as ciclosporin or methotrexate.

This product contains lactose monohydrate, glucose and sorbitol. If you have been told by your doctor that you have an **intolerance** to some sugars **do not take** Echinacea Cold Relief.

Take special care with Echinacea Cold Relief

- If there is a family history of allergic reactions.
- Because echinacea can trigger auto-immune diseases.

Taking other medicines

Please tell your doctor or qualified healthcare practitioner if you are taking any other medicines.

Pregnancy and breast-feeding

Do not take Echinacea Cold Relief if you are pregnant or breast-feeding, because there is no evidence that it is safe to do so. Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take Echinacea Cold Relief

For oral short term use only.

Take Echinacea Cold Relief as advised in this leaflet. You should check with your doctor or qualified healthcare practitioner if you are not sure.

Do not exceed the stated dose.

Chew the tablet or swallow it whole with water.

Adults, elderly and children over 12 years

Take 2 to 3 tablets 3 times a day.

Do not take more than 9 tablets a day.

This tablet formulation is not intended for children under 12 years.

Start your treatment at the first signs of common cold.

Do not use for more than 10 days.

Contact your doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after 10 days.

FM407052GB-2

22407052

If you take more Echinacea Cold Relief than you should

If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you. Because of the sugar content taking too much Echinacea Cold Relief may cause diarrhoea.

If you forget to take Echinacea Cold Relief

Continue to take your usual dose at the usual time. It does not matter if you have missed a dose. Do not take a double dose to make up for forgotten tablets.

If you have any further questions on the use of this product, ask your doctor or a qualified healthcare practitioner.

4. Possible side effects

Like all medicines, Echinacea Cold Relief can cause side effects, although not everybody gets them.

The frequency of the side effects is not known.

The possible side effects include:

- Skin rash.
- Red, itchy skin (hives).
- Swelling of the skin due to fluid (angioedema).
- Swelling of the face (Quincke's oedema).
- Blistering of the skin and mucous membranes (Stevens-Johnson Syndrome).
- Difficulty in breathing (bronchospasm with obstruction).
- Asthma and life threatening reactions (anaphylactic shock).

Echinacea Cold Relief can trigger allergic reactions in patients who have a tendency to allergic reactions.

Stop taking Echinacea Cold Relief immediately if you experience any allergic reaction.

Association with diseases of the immune system (autoimmune diseases) have been reported with the use of echinacea such as:

- Inflammation of the brain and spinal chord (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 kidney tubular dysfunction (Sjögren syndrome).

A decrease in the number of white blood cells (leucopenia) may occur in long term use (more than 8 weeks).

If you are concerned about any side effect, if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or qualified healthcare practitioner. You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.yellowcard.gov.uk. Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call freephone 0808 100 3352 (available 10 am–2 pm Monday–Friday).

5. How to store Echinacea Cold Relief

Do not store above 25°C.

Keep out of the reach and sight of children.

Do not use Echinacea Cold Relief after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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

6. Further information

What Echinacea Cold Relief contains

- Each film-coated tablet contains 40 mg of extract (as dry extract) (6.5:1) equivalent to 260 mg of Echinacea purpurea root (*Echinacea purpurea* L. Moench).
Extraction solvent: Ethanol 45% V/V.
- The **other ingredients** are liquorice extract, menthol, hydrated dextrate, sorbitol, talc, microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, eucalyptus oil, anise oil, fennel oil, clove oil, 7 mg lactose monohydrate, cellulose, colloidal anhydrous silica dioxide.

What Echinacea Cold Relief looks like and contents of the pack

The film-coated tablets are brown/grey-speckled and round.
Pack sizes: 40, 60, 80 tablets in blisters.
Not all pack sizes may be marketed.

Traditional Herbal Registration Holder

Pharbio Medical International AB,
Box 715, SE-194 27 Upplands Väsby,
Sweden.
Telephone: +46 8 590 963 00
E-mail: regulatory@cederth.com

Manufacturer

Cederth International Production
Paramedical A/S,
Vassingerødvej 3-7, DK-3540 Lyngø,
Denmark.

Manufactured for

Holland & Barrett Retail Ltd,
Nuneaton, Warwickshire CV11 6XW, UK

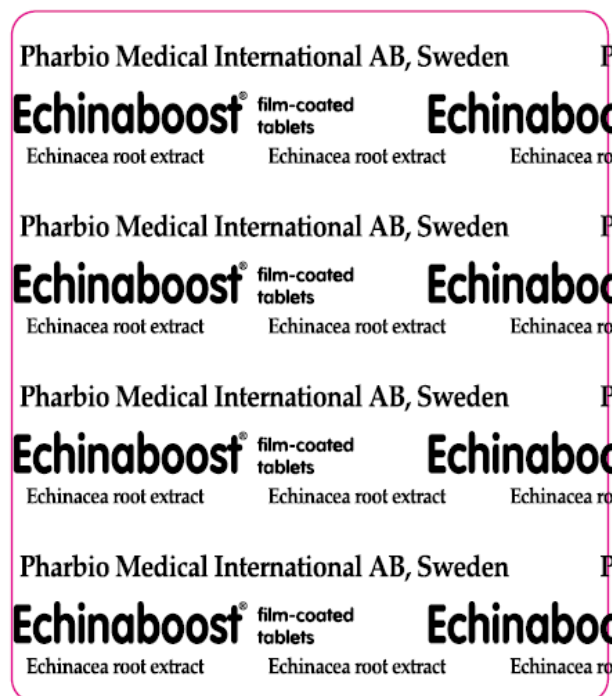
This leaflet was last approved in November 2010



CERTIFICATION MARK

LABELLING

Blister:



Carton:



Blister:



Carton:



Herbal Classics Echinacea
Cold Relief