

PACKAGE LEAFLET: INFORMATION FOR THE USER

Echinaforce Cold & Flu oral drops Echinacea purpurea herb & root tinctures

Read all of this leaflet carefully before you start taking this product because it contains important information for you.

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

What is in this leaflet:

1. What Echinaforce is and what it is used for
2. What you need to know before you take Echinaforce
3. How to take Echinaforce
4. Possible side effects
5. How to store Echinaforce
6. Contents of the pack and other information

1. WHAT ECHINAFORCE IS AND WHAT IT IS USED FOR

Echinaforce is a traditional herbal medicinal product containing the extracts of fresh *Echinacea purpurea* herb and root.

It is used to relieve:

- Common cold symptoms
- Flu-like symptoms

This is exclusively based on long-standing use.

Echinaforce is for use in adults and adolescents over 12 years of age.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ECHINAFORCE

Do not take Echinaforce

- If you are under 12 years of age.
- If you are **allergic** to
 - Echinacea or plants of the daisy (Asteraceae/Compositae) family. Echinacea is a member of the daisy family.
 - Any of the other ingredients of this product (listed in section 6).

- If you **suffer** from
 - TB (the infection tuberculosis)
 - Sarcoidosis (a connective tissue disorder which causes the formation of clumps of cells, mainly in the lymph nodes, lungs and liver)
 - An autoimmune disease such as collagenoses (inflammation of the connective tissue) or multiple sclerosis
 - HIV, AIDS or any other condition which decreases your resistance to infection
 - A disorder which affects your white blood cells such as agranulocytosis (low white blood cell count due to bone marrow disorders) or leukemia (blood cell cancer)
- If you are having treatment to reduce the response of your immune system (immunosuppression) e.g. chemotherapy, radiotherapy
- If you have had an organ or bone marrow transplant

Warnings and precautions

- Stop taking this product and see your doctor if:
 - You have a high temperature (fever)
 - Your symptoms worsen or if you do not feel an improvement within 10 days
- If you have a tendency to allergies such as hives, allergic eczema or asthma consult your doctor before use. This product may not be suitable for you.

Children

- Do not give this product to children under 12 years of age.

Other medicines and Echinaforce

- Do not take this product if you are already taking another medicine which is affected by alcohol.
- Do not take this product if you are taking any medicine which affects your immune system.
- If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as Echinaforce.

Pregnancy and breast-feeding

- Do not take this product if you are pregnant or breast-feeding.

Driving and using machines

- This product contains alcohol (see below for alcohol content). Overdose of this product may result in alcohol intoxication.

Echinaforce contains alcohol

- This product contains 65 vol % ethanol (alcohol), i.e. up to 366 mg per 20 drop dose, equivalent to 9 ml beer (less than a tablespoon) or 4 ml wine (less than a teaspoon) per dose.
- Harmful for those suffering from alcoholism.
- To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

3. HOW TO TAKE ECHINAFORCE

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Recommended dose

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

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

For oral short-term use only. Do not take more than the recommended dose.

If you take more Echinaforce than you should

- If you take too much and feel ill, talk to your doctor.
- Overdose of this product may result in alcohol intoxication.

If you forget to take Echinaforce

- Do not worry about a missed dose. Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all products, this product can cause side effects, although not everybody gets them.

Side effects

Allergic reactions

If you already suffer from allergies you may be more likely to get them. Allergic reactions which may occur are:

- Skin rash
- Red, itchy skin (hives)
- Swelling of the face or skin due to fluid (angioedema)
- Blistering of the skin, mouth, eyes or groin (Stevens-Johnson syndrome)
- Difficulty in breathing
- Asthma or anaphylactic shock (a life-threatening allergic reaction)

Stop taking this product immediately if any of these occur. Seek medical advice and take this leaflet with you.

Other effects

You may find that when you take Echinaforce you feel tingling, irritation or numbness in your mouth. This is due to the presence of alkylamides which are a natural part of the plant extracts in Echinaforce.

There have been isolated reports suggesting an association between Echinacea products and autoimmune diseases such as:

- Inflammation of the brain and spinal cord (multiple sclerosis)
- Painful lumps on the shins (erythema nodosum)
- Low blood platelet count
- Destruction of blood cells by antibodies (Evans Syndrome)
- Dryness in the mouth and eyes with kidney dysfunction (Sjögren Syndrome)

The frequency of the above side effects is not known. This means it is not known how often these reactions occur as there has not been enough reports to allow this information to be calculated.

Reporting of side effects

- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You can also report side effects directly via:
HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie
- By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ECHINAFORCE

- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Use within 4 months of opening.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in appearance. It should be a clear liquid that is olive-green in colour.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Echinaforce contains

One dose (20 drops) contains the tinctures of:

Fresh Echinacea herb **614 mg**

(*Echinacea purpurea* (L.) Moench) (1:12-13)

Extraction solvent: Ethanol 65% V/V

Fresh Echinacea root **32 mg**

(*Echinacea purpurea* (L.) Moench) (1:11-12)

Extraction solvent: Ethanol 65% V/V

1 ml of Echinaforce Cold & Flu oral drops is equivalent to 28 drops.

The other ingredients used for the liquid are ethanol and purified water.

What Echinaforce looks like and the contents of the pack

Echinaforce drops are clear, oral drops that are olive-green in colour. Echinaforce is available in 15 ml, 50 ml and 100 ml bottles. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder

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You should also know

A.Vogel Ireland runs a helpline by phone and email which can provide you with further information.

E-mail: enquiries@avogel.ie

Phone: 0818 930 070

You can get a larger print or audio version of this leaflet. Call this number: 0818 930 070.