

Package Leaflet: Information for the user

Echinaforce®

Hot Drink

Cold & Flu

Echinacea concentrate

for oral solution

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

1. WHAT ECHINAFORCE HOT DRINK CONCENTRATE IS AND WHAT IT IS USED FOR

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ECHINAFORCE HOT DRINK CONCENTRATE

Do not take Echinaforce Hot Drink Concentrate

- 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 disease 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 Hot Drink Concentrate

- 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 Hot Drink Concentrate.

Pregnancy and breast-feeding

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

Driving and using machines

- Echinacea has no known effect on your ability to drive or use machines. Make sure you know how this product affects you before your drive or use machinery.

Echinaforce Hot Drink Concentrate contains sucrose and alcohol

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.
- This product contains 4.12 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus.
- This medicine contains 33 mg of alcohol (ethanol) in each 5 ml dose. The amount in each dose (5 ml) of this medicine is equivalent to less than 1 ml beer or 1 ml wine.
- The small amount of alcohol in this medicine will not have any noticeable effects.

3. HOW TO TAKE ECHINAFORCE HOT DRINK CONCENTRATE

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.

To be made into a hot drink by diluting in hot water before use.

Diagram

1. Shake the bottle before use. Fill the 5 ml measuring spoon provided with the product
2. Pour the contents of the spoon into a cup
3. Add hot water and stir

Recommended dose

Adults, older people and adolescents over 12 years:

Days 1 to 3: Take 5 ml diluted in hot water five times daily

Days 4 to 10: Take 5 ml diluted in hot water three times daily

Start taking the 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 Hot Drink Concentrate than you should

- If you take too much and feel ill, talk to your doctor.

If you forget to take Echinaforce Hot Drink Concentrate

- 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 Hot Drink Concentrate 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 Hot Drink Concentrate.

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

- Inflammation of the brain and spinal cord (disseminated encephalitis)
- Painful lumps on the shins (erythema nodosum)
- Low 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
Website: www.hpra.ie
- By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ECHINAFORCE HOT DRINK CONCENTRATE

- 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.
- Store below 25°C.

- After opening, store in the refrigerator (below 8°C).
- Use within 1 month of opening.
- Do not use this product if you notice a change in appearance. It should be a viscous liquid that is dark red to dark violet in colour.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Echinaforce Hot Drink Concentrate contains

5 ml of concentrate for oral solution contains 1,140 mg of extract (as tincture) of fresh *Echinacea purpurea* (L.) Moench herb (1:12-13) and 60 mg of extract (as tincture) of fresh *Echinacea purpurea* (L.) Moench root (1:11-12). Extraction solvent: Ethanol 65% V/V.

The other ingredients used are sucrose, purified water, concentrated elderberry juice, citric acid monohydrate, modified starch, medium-chain triglycerides and potassium sorbate.

What Echinaforce Hot Drink Concentrate looks like and the contents of the pack

Echinaforce Hot Drink Concentrate is a dark red to dark violet viscous liquid with a fruity elderberry-like smell and a fruity, sweet and slightly sour taste. It is available in 100 ml bottles.

Traditional Herbal Registration Holder

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What is Echinacea?

Echinacea is a plant which is native to America. The herb and root extracts of the Echinacea species, *Echinacea purpurea*, are combined to make Echinaforce Hot Drink Concentrate.

You should also know

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

Email: 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.