

Package Leaflet:
Information for the user

A.Vogel

Echinaforce®

Sore Throat Spray
Echinacea & Sage extracts



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 7 days.

What is in this leaflet

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

1. What Echinaforce Sore Throat Spray is and what it is used for

Echinaforce Sore Throat Spray is a traditional herbal medicinal product containing the extracts of fresh *Echinacea purpurea* herb and root and fresh Sage leaves.

It is used to relieve sore throats associated with coughs, colds and flu-like illnesses. This is exclusively based on long-standing use.

Echinaforce Sore Throat Spray is for use in adults and older people over 18 years of age.

2. What you need to know before you use Echinaforce Sore Throat Spray

Do not use Echinaforce Sore Throat Spray

- If you are **allergic** to
 - Echinacea or plants of the daisy (Asteraceae/Compositae) family. Echinacea is a member of the daisy family.
 - Sage.
 - Peanut or soya. This product contains soy lecithin.
 - 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 leukaemia (blood cell cancer)
- If you are having treatment that reduces the response of your immune system (immunosuppression) e.g. chemotherapy, radiotherapy.
- If you have had an organ or bone marrow transplant.

Warnings and precautions

- If you have a tendency to allergies such as hives, allergic eczema or asthma consult your doctor **before** using this product. This product may not be suitable for you.
- See your doctor if **during** the use of this product
 - You have problems swallowing or breathing.

- Your sore throat is severe and you have a high temperature (fever), headache or if you feel sick or are being sick.
- Your symptoms worsen or if you do not feel an improvement within 7 days.
- Avoid getting this product in your eyes. If you accidentally spray it into your eyes, rinse thoroughly with water.

Children and adolescents

- Do not give this product to children or adolescents under 18 years of age.

Other medicines and Echinaforce Sore Throat Spray

- Do not use this product if you are taking any medicine which affects your immune system.
- Do not use this product if you are taking barbiturates or benzodiazepines (used as tranquillisers).
- Do not use this product if you are already taking another medicine which is affected by alcohol.
- 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 Sore Throat Spray.

Pregnancy and breast-feeding

- Do not use 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.

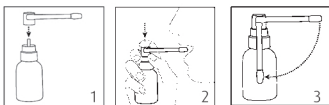
Echinaforce Sore Throat Spray contains soya, sucrose, alcohol and sorbitol

- If you are allergic to peanut or soya, do not use this product.
- If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this product.
- This medicine contains 129 mg of sorbitol in each dose (2 sprays).
- Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take this product.
- This medicine contains 163 mg of alcohol (ethanol) in each dose.
- The amount in each dose of this medicine is equivalent to less than 5 ml beer (around a teaspoon) or 2 ml wine (less than half a teaspoon).
- The small amount of alcohol in this medicine will not have any noticeable effects.



3. How to use Echinaforce Sore Throat Spray

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.



1. Fit the nozzle onto the top of the bottle. Before using this product for the first time press the pump 2-3 times to activate the spray.
2. To use the spray shake the bottle well, place the nozzle just inside your mouth and point it towards the back of your throat. Press the pump to spray.
3. After use, turn the nozzle back down.

Recommended dose

Adults and older people over 18 years: 2 sprays six to ten times daily.

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

If you take more Echinaforce Sore Throat Spray than you should

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

- Overdose of this product may result in alcohol intoxication and should be treated accordingly.

If you forget to take Echinaforce Sore Throat Spray

- 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:

Common

- Rash inside the mouth
- Burning sensation in the throat

Frequency not known

- 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 use Echinaforce Sore Throat Spray 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)

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

The frequency of the above side effects is not known. This means it is not known how often these reactions occur as there have 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 1 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 Sore Throat Spray

- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date (EXP) which is stated on the label and carton. The expiry date refers to the last day of that month.
- Use within 2 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 brown to yellow-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 Sore Throat Spray contains

Each 2 spray dose contains the tinctures of:

Fresh Echinacea herb 379.9 mg
(*Echinacea purpurea* (L.)) (1:12-13)
Extraction solvent: Ethanol 65% V/V

Fresh Echinacea root 20.0 mg
(*Echinacea purpurea* (L.)) (1:11-12)
Extraction solvent: Ethanol 65% V/V

Fresh Sage leaves 189.2 mg
(*Salvia officinalis* (L.)) (1:17-18)
Extraction solvent: Ethanol 68% V/V

The other ingredients in the spray are sucrose laurate, soy lecithin, ethanol, peppermint oil and sorbitol liquid.

What Echinaforce Sore Throat Spray looks like and contents of the pack

Echinaforce Sore Throat Spray is a clear, liquid oromucosal spray that is brown to yellow-green in colour. Echinaforce Sore Throat Spray is available in 30 ml bottles.

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**