





Echinaforce®
Echinacea Tablets



17429 Echinaforce tablets PIL UK Variation RFI Aug 2012.indd 1

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Important things you need to know

- This product is used to relieve the symptoms of cold and flu.
- This product is suitable for children over 12 years.
- Don't take this product if you are allergic to lactose or any of the other ingredients in this product: see section 6.
- Before you take this product: read section 2.
- Dosage instructions: see section 3.
- Talk to your doctor if your symptoms worsen or do not improve within 10 days.
- Side effects can rarely occur when using this product: see section 4.

Now read the rest of this leaflet carefully. Keep this leaflet. You may need to read it again.

1. What this product is for

Echinaforce is a traditional herbal remedy used to relieve the symptoms of:

- Cold
- Flu
- Upper respiratory tract infections

Echinaforce helps maintain the body's resistance by supporting the immune system.



this product

2. Before you take

For children under 12 years of age.

If you are allergic to

Do not use this product

- Echinacea or plants of the daisy (Asteraceae/ Compositae) family.
 Echinacea is a member of the daisy family.
- Any of the other ingredients in this product (see section 6)
- If you have been told by your doctor that you have an intolerance to products containing lactose. This product contains lactose.
- 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.
- If you are pregnant or breastfeeding.
- 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 are taking ciclosporin or methotrexate, or any other immunosuppressant medicine.
- If you have had an organ or bone marrow transplant.



3. How to take this product

Adults, elderly and children over 12 years: Take 2 tablets two to three times daily.

Not for use in children under 12.

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

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

Do not take this product for a cold or flu for more than 10 days.

If you take too much

 If you take too much and feel ill, talk to your doctor. Taking too much is unlikely to be harmful.

If you forget to take this product

 Don't worry about the missed dose. Take the next dose as usual.

Please turn over...









If you feel this product isn't working

Stop taking this product and see your doctor:

- If you have a high temperature (fever)
- If your symptoms worsen or if you don't feel an improvement within 10 days
- Adverse events not mentioned in the patient information leaflet occur



Side effects

4. Possible side effects

Like all medicines, 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 skin due to fluid (angioedema) or swelling of the face (Quincke's oedema)
- Blistering of the skin and mucous membranes (Stevens-Johnson syndrome)
- Difficulty in breathing (bronchospasm with obstruction)
- 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.

There have been isolated reports suggesting an association between Echinacea products and autoimmune diseases 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. 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.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



Information

5. How to store this product

- Keep out of the reach and sight of children.
- Do not use this product after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not use this product if you notice a change in appearance.
 The tablets should be greenish in colour.

6. Further Information

What this product contains

1 tablet contains 380 mg of extract (as dry extract) from fresh *Echinacea purpurea* (L.) Moench herb (1:7.5-14.6) and 20 mg of extract (as dry extract) from fresh *Echinacea purpurea* (L.) Moench root (1:7.1-12.5). Extraction solvent: ethanol 65% v/v.

The other ingredients used for the tablet are potato starch, magnesium stearate and lactose

What this product looks like and the contents of the pack

The tablets are round and greenish in colour. This product is available in packs containing 42 and 120 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder and Batch Release:

Bioforce (UK) Ltd, 2 Brewster Place, Irvine, Ayrshire, UK KA11 5DD

Manufacturer:

Bioforce AG, CH-9325, Roggwil Switzerland

PL No. 13668/0001

This leaflet was revised on 08/2012

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 Echinacea Tablets.

You should also know

Bioforce runs a helpline by phone and email which can provide you with further information.

Email: enquiries@avogel.co.uk Phone: 0845 608 5858

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.
Alternatively you can get a paper Yellow Card form from your doctor's surgery or pharmacy, or call freephone 0808 100 3352 (available 10am-2pm Monday-Friday).

You can get a larger print or audio version of this leaflet.
Call this number: 0845 608 5858.

