

Sona[®]

Echinace

Tablets

Echinacea purpurea root dry extract

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

This medicine is available without prescription; however, you still need to use this medicine carefully to get the best results from it. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

Keep this leaflet as you may need to read it again. Ask a qualified healthcare professional e.g. a doctor or pharmacist if you need more information or advice.

You must contact a qualified healthcare professional e.g. a doctor or pharmacist if you do not feel better or if you feel worse after 10 days.

If you get any side effects, talk to your qualified healthcare professional e.g. a doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

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

1. What is Echinace Tablets and what is it used for?

This medicine contains:

• Echinacea purpurea root dry extract

A traditional herbal medicinal product used to relieve common cold and flu-like symptoms in adolescents & adults over 12 years of age, exclusively based on longstanding use.

2. What you need to know before you take Echinace Tablets?

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

DO NOT take Echinace Tablets 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 this product. (See section 6 for further information).

DO NOT take Echinace Tablets if you suffer from:

- Frequent allergic reactions such as hives (urticaria), eczema, asthma
- The infection: tuberculosis
- Sarcoidosis (a connective tissue disease which causes the formation of clumps of cells, mainly in the lymph nodes, lungs and liver)
- Autoimmune diseases such as the collagenoses (inflammation of the connective tissue) or multiple sclerosis
- Conditions which decrease your natural response to infection (e.g. HIV infection or AIDS)
- Blood disorders involving the white blood cell system such as low white cell count due to bone marrow disorders (agranulocytosis) or blood cell cancer (leukemias)

DO NOT take Echinace Tablets if:

- You are on therapy that reduces your natural response to infection (e.g. chemotherapy or radiotherapy for cancer)
- You have a history of organ or bone marrow transplant

Warnings and precautions:

Take special care with Echinace Tablets:

- If there is a family history of allergic reactions
- Because Echinacea can trigger auto-immune diseases
- Tell your doctor if your symptoms worsen or persist after you have taken Echinace Tablets for 10 days.

Taking other medicines:

DO NOT TAKE this product if you are taking any medicine that affects your immune system. Please tell your doctor or pharmacist if you are taking any other medicines, including those obtained without a prescription.

Pregnancy and breast feeding and fertility:

DO NOT TAKE this medicine if you are pregnant or breast feeding, because there is no evidence that it is safe to do so.

Driving and using machines:

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

3. How to take Echinace Tablets

For oral short-term use only.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Start at the first signs of a common cold. Swallow the tablets whole with water. Do not chew.

The recommended dose is:

Adults, elderly and adolescents over 12 years: Take 1 tablet, three times a day, if required.

Do not give to children under 12 years.

Do not exceed the stated dose.

If the condition worsens or high fever occurs whilst taking the product or if symptoms persist for more than 10 days, see a qualified healthcare professional e.g. a doctor or pharmacist.

If you take more than the recommended dose of Echinace, you should contact your qualified healthcare professional e.g. a doctor or pharmacist straight away.

If you forget to take Echinace Tablets, do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your qualified healthcare professional e.g. a doctor or pharmacist.

4. Possible side effects

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

The frequency of the side effects is not known.

The possible side effects include:

- allergic reactions such as hives or rashes
- swelling of the skin or face due to fluid
- difficulty breathing
- asthma
- anaphylactic shock
- blistering of the skin, mouth, eyes or groin (Stevens-Johnson Syndrome)

Echinacea can trigger allergic reactions in patients who have a tendency to allergic reactions. Stop taking the product immediately if you experience any allergic reaction.

Association with auto-immune diseases has been reported 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 eye with kidney dysfunction (Sjogren Syndrome).

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

Reporting of side effects

If you are concerned about any side effect, if a side effect becomes serious, or if you notice a side effect not listed in this leaflet, please tell a qualified healthcare professional e.g. your doctor, pharmacist or nurse.

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 Echinace Tablets

Keep this medicine out of the reach and sight of children.

Do not use these tablets after the expiry date printed on the carton and on the blister. The expiry date refers to the last day of the month. Do not store above 25°C. Store in the original container. Do not throw away any medicines via 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

Each film coated tablet contains 127.0 mg of extract (dry extract) from *Echinacea purpurea* root (6-7:1) (equivalent to 762 mg – 889 mg of *Echinacea purpurea* (L.) Moench root).

Extraction solvent: Ethanol 30% v/v.

The other ingredients are maltodextrin, calcium hydrogen phosphate dihydrate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, hypromellose, purified talc, titanium dioxide (E171), yellow iron oxide (E172).

This medicine is available in pack sizes of 30, 60, 120 and 180 film coated tablets. Not all pack sizes are marketed.

Traditional registration holder: Sona Nutrition Ltd., Unit 3 Westgate Business Park, Ballymount, Dublin 24, Ireland.

Manufacturer: Brunel Healthcare Manufacturing Ltd, William Nadin Way, Swadlincote, Derbyshire, DE11 0BB, U.K.