



ECHINACEA COLD AND FLU HARD CAPSULES

Echinacea purpurea root extract

Important notes

Please read this leaflet carefully before you take this traditional herbal medicine because it contains important information for you

- Always take this traditional herbal medicine exactly as described in this leaflet or as your doctor or pharmacist has told you
- Keep this leaflet. You may need to read it again
- Ask a healthcare professional eg a doctor or a pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet
- You must talk to a doctor if you feel worse or you do not feel better after 10 days of taking this traditional herbal medicine

What is in this leaflet

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1 - What this traditional herbal medicine is and what it is used for

Nature's Bounty Echinacea Cold and Flu Hard Capsules is a traditional herbal medicinal product used to relieve common cold and flu-like symptoms in adults and adolescents over 12 years. This is exclusively based upon long-standing use.

2 - What you need to know before you take this traditional herbal medicine

Do not take this traditional herbal medicine if you:

- Are allergic to Echinacea or traditional herbal medicines from the same plant family (Asteraceae/Compositae) such as daisies, marigolds or artichokes, or to any of the other ingredients in this traditional herbal medicine (listed in section 6 of this leaflet)
- Suffer from Sarcoidosis (a connective tissue disorder which causes the formation of clumps of cells, mainly in the lymph nodes, lungs and liver)
- Are having treatment that reduces your natural response to infection (eg chemotherapy or radiotherapy)
- Suffer from autoimmune conditions such as inflammation of the connective tissue (collagenosis) or multiple sclerosis
- Suffer from conditions which decrease your resistance to infection (eg HIV or AIDS)
- Suffer from TB (The infection tuberculosis)
- Have had an organ or bone marrow transplant
- Suffer from blood disorders involving the white blood cell system such as low white blood cell count due to bone marrow disorders (agranulocytosis) or blood cell

cancer (leukaemia)

Warnings and Precautions

Talk to your doctor or pharmacist before taking this traditional herbal medicine if you:

- Suffer from frequent allergic reactions such as hives, eczema or asthma

Do not take this traditional herbal medicine for more than 10 days. If your symptoms worsen or persist for more than 10 days, if new symptoms develop, or if high fever occurs whilst taking this traditional herbal medicine, consult your doctor or pharmacist.

Children: Do not give this traditional herbal medicine to children under 12 as it is not known if it is safe to do so.

Other medicines and Nature's Bounty Echinacea Cold and Flu Hard Capsules: Always remember to tell your doctor or pharmacist about any medication you are taking including herbal medicines such as this one or other medicines that didn't require a prescription. Do not take this traditional herbal medicine if you are taking any medicines that affect your immune system.

Pregnancy, breastfeeding and fertility: Do not take this traditional herbal medicine if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby as it is not known if 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 traditional herbal medicine affects you before you drive or use machinery.

3 - How to take this traditional herbal medicine

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

For oral short-term use only.

Adults, older people and adolescents over 12 years:

Take 1 capsule 2 times daily. Swallow the whole capsule with water. Start at the first sign of a common cold.

The maximum dose is 2 capsules per day.

Do not exceed the stated dose.

Do not take this traditional herbal medicine for more than 10 days. If your symptoms worsen or persist for more than 10 days, or if new symptoms develop, or if high fever occurs whilst taking this traditional herbal medicine, consult your doctor or pharmacist.

If you take too much of this traditional herbal medicine (overdose): Speak to a qualified healthcare professional eg a doctor or pharmacist immediately and take this leaflet and bottle with you.

If you forget to take this traditional herbal medicine:

Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

If you have any further questions on the use of this traditional herbal medicine, ask a doctor or pharmacist.

More information on back panel

4 - Possible side effects

Possible side effects are:

- Allergic reactions such as hives or rashes
- Swelling of the face or skin due to fluid
- Difficulty breathing
- Asthma or anaphylactic shock (a life threatening allergic reaction)
- 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 this traditional herbal medicine immediately if you experience any allergic reaction.

Association with autoimmune diseases have 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 tubular dysfunction (Sjogren's syndrome)

A decrease in the number of white blood cells may occur with 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 • Email: medsafety@hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

5 - How to store this traditional herbal medicine

- Keep this traditional herbal medicine out of sight and reach of children
- Keep this traditional herbal medicine in the bottle until it is time to take it
- Do not use this traditional herbal medicine after the expiry date which is stated on the carton and bottle label after 'EXP'. The expiry date refers to the last day of that month
- Do not store above 25°C
- Keep the bottle tightly closed in order to protect from light and moisture

6 - Contents of the pack and other information

What this traditional herbal medicine contains: Each hard capsule contains 140mg of extract (as dry extract) from *Echinacea purpurea* root (equivalent to 838mg-1117mg of *Echinacea purpurea* (L.) Moench (purple coneflower) root). Extraction solvent: Ethanol 75% v/v.

This traditional herbal medicine also contains the following inactive ingredients (excipients):

Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.

Inactive ingredients in the extract: Maltodextrin, Silica colloidal anhydrous.

Capsule Shell: Hypromellose.

What Nature's Bounty Echinacea Cold and Flu Hard Capsules look like and contents of the pack: Each bottle contains 30, 60 or 100 clear two piece capsules with grey/brown fill.

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Traditional Herbal Registration Holder

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If you would like further information about this traditional herbal medicine, please contact:

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