



MILK THISTLE HARD CAPSULES

Milk Thistle Standardised Fruit 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 do not feel better after 1 week 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

A traditional herbal medicinal product for the symptomatic relief of digestive disorders such as indigestion, feeling of fullness and flatulence, 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:

- Under 18 years of age
- Allergic to Milk Thistle or plants of the Asteraceae/Compositae family such as daisies, marigolds or artichokes
- Allergic to any ingredients in this traditional herbal medicine (listed in section 6 of this leaflet)

Warnings and Precautions

Talk to your doctor or pharmacist before taking this traditional herbal medicine if you are currently suffering from active liver disease.

Children and adolescents: Do not give this traditional herbal medicine to children or adolescents under 18 years as it is not known if it is safe to do so.

Other medicines and Nature's Bounty Milk Thistle Hard Capsules including traditional herbal medicines: Tell your doctor or pharmacist if you are taking, have recently or might take any other medicines, including herbal medicines such as this one, or other medicines that didn't require a prescription.

Pregnancy, breastfeeding and fertility: Do not take this traditional herbal medicine if you are pregnant, breastfeeding or planning to have a baby, as it is not known if it is safe to do so.

Driving and using machines: Milk Thistle Hard Capsules have 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 over 18 years and older people:

Take 1 capsule 2 times daily. Swallow the whole capsule with water.

The maximum dose is 2 capsules per day.

Do not exceed the stated dose.

Do not take this traditional herbal medicine for more than 1 week. Please see your doctor or pharmacist if your symptoms worsen or persist for more than 1 week of taking this traditional herbal medicine.

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

More information on back panel

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.

4 - Possible side effects

Possible side effects are:

- Nausea (feeling sick)
- Diarrhoea
- Upset stomach
- Headache
- Anaphylaxis (a sudden, severe allergic reaction with swelling and breathing difficulties - medical help should be sought immediately)
- Mild allergic reactions such as itching and/or skin rash, urticaria, hives, pruritus

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 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 133mg-324mg of extract (as dry extract) from Milk Thistle Fruit (*Silybum marianum* (L.) Gaertn) (equivalent to 3325mg-9720mg of Milk Thistle fruits) corresponding to 108mg of silymarin, calculated as silibinin.

Extraction solvent: Acetone 99.9% 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.

Capsule shell: Hypromellose.

What Nature's Bounty Milk Thistle Hard Capsule look like and contents of the pack: Each bottle contains 30 or 50 clear, two piece hard capsules with beige/brown fill.

TR 23157/014/001

Traditional Herbal Registration Holder

Holland & Barrett Limited
Regulatory Services Department
Cedar Drive, Dublin Airport Logistics
Park, St. Margarets, Co. Dublin
K67 E0C5
Ireland

Manufacturer

Wiewelhove GmbH,
Dörnebrink 19, 49479 Ibbenbüren, Germany

If you would like further information about this product, please contact:

Holland & Barrett Limited
Regulatory Services Department
Cedar Drive, Dublin Airport Logistics Park
St. Margarets, Co. Dublin
K67 E0C5
Ireland

Telephone: +353 (1) 517 6229

Email: customerservices@hollandandbarrett.com

This leaflet was prepared on: 20/02/2021