



## Milk Thistle Capsules

Active ingredient: 200 mg milk thistle dry fruit extract

Soft capsules

To be taken by adults

**Read the entire information leaflet carefully; it contains important information for you. This medicinal product is available without a prescription. However, in order to achieve the best possible treatment Milk Thistle Capsules must be taken as prescribed.**

- Keep this information leaflet. You may want to reread it at a later date.
- Ask your pharmacist if you need any additional information or advice.
- Please inform your doctor or pharmacist if you are seriously affected by one of the listed side effects or if you notice side effects that are not included in this information leaflet.

### **This information leaflet contains:**

1. What are Milk Thistle Capsules and what are they used for?
2. What must I be aware of before taking Milk Thistle Capsules?
3. How should Milk Thistle Capsules be taken?
4. Which side effects are possible?
5. How should Milk Thistle Capsules be stored?
6. Additional information

### **1. What are Milk Thistle Capsules and what are they used for?**

#### **Areas of application:**

Milk Thistle Capsule is a traditional herbal medicine to support digestive system by stimulating the function of the liver and gall system.

This medicine is a traditional medicine that is exclusively registered on the basis of years of application for the application areas

### **2. What must I be aware of before taking Milk Thistle Capsules?**

#### **Milk Thistle Capsules must not be taken:**

- if you are allergic to milk thistle and other composite plants, to soya, peanut or any of the other ingredients of this medicine listed in section 6 - in the case of liver disease
- in the case of gall stones
- in the case of obstruction to the bile duct
- in the case of an inflamed bile duct or gall bladder.

#### **Special care should be taken when taking Milk Thistle Capsules:**

If you suffer from persistent, inexplicit or newly appearing medical complaints you should consult your doctor, as it could be a symptom of an illness that requires medical treatment.

#### **The following should be noted when taking Milk Thistle Capsules with other medicinal products:**

No research has been conducted into the interaction between Milk Thistle Capsules and other medicines.

It cannot be ruled out that the anti-arrhythmic effect of amiodarone is increased when Milk Thistle Capsules are taken at the same time as amiodarone (medicine used to combat cardiac arrhythmia).

Please inform your doctor or pharmacist if you take, or have recently taken, other medicinal products even if they are non-prescription medicinal products.

#### **When taking Milk Thistle Capsules together with food and drink:**

There are no known side effects with food and drink.

**Pregnancy and lactation:**

Please ask your doctor or pharmacist for advice if you are pregnant or are nursing, if you think you might be pregnant or intend to become pregnant.

Insufficient research has been conducted into safety during pregnancy and lactation. Milk Thistle Capsules are therefore not recommended for pregnant and nursing women.

**Children and young people:**

Insufficient research has been conducted into children and youngsters taking this medicinal product. Milk Thistle Capsules should, therefore, not be taken by people under the age of 18.

**Fitness to drive and operate machinery:**

There are no known adverse effects.

**Milk Thistle Capsules contain sorbitol.**

This medicinal product contains 23.48 mg sorbitol per soft capsule. Sorbitol is a source of fructose. Talk to your doctor before taking or receiving this medicine 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 congenital condition in which a person cannot break down fructose.

**3. How should Milk Thistle Capsules be taken?**

Always take Milk Thistle Capsules as described in the instructions in this information leaflet. Please consult your doctor or pharmacist if you are unsure.

**The normal dose for adults is:**

1 soft capsule twice a day.

Insufficient data is available for concrete dosage recommendations for limited bladder kidney function.

**How to take the medicine:**

Swallow the soft capsules whole with sufficient liquid, ideally a glass of water, prior to mealtimes.

**Children and young people:**

Insufficient research has been conducted into children and youngsters taking this medicinal product. Milk Thistle Capsules should, therefore, not be taken by people under the age of 18.

**How long to take the medicine for:**

In the case of complaints with an unknown cause, self-medication should be ended after two weeks.

In the case of on-going symptoms or the occurrence of side effects not listed in this information leaflet, you should consult a doctor or another qualified health professional.

Please note the information contained in Section 2 "Special care should be taken when taking Milk Thistle Capsules."

Please consult your doctor or pharmacist if you feel that the Milk Thistle Capsules are having too great or too little an effect.

**What to do if you take too many Milk Thistle Capsules:**

Accidentally taking this medicinal product in a higher dosage may have a mild laxative effect. Consult your doctor if you experience other symptoms. Your doctor can decide on the best course of action.

**If you forget to take Milk Thistle Capsules:**

Do not take a double dose; instead take the dose as described in this information leaflet or as instructed by your doctor.

**If you stop taking Milk Thistle Capsules:**

It is generally considered harmless to stop the treatment or to end it prematurely. If you have any further questions about taking this medicinal product please consult your doctor or pharmacist.

**4. Which side effects are possible?**

Gastrointestinal complaints and allergic reactions, e.g. rash and breathlessness may occur.

There is no information about the frequency of these possible side effects.



Soya proteins can very rarely cause an allergic reaction.

Please inform your doctor or pharmacist if you notice side effects that are not included in this information leaflet.  
Do not take Milk Thistle Capsules if you experience any kind of allergic reaction.

#### **Reporting side effects:**

Please inform your doctor or pharmacist if you notice side effects. This also applies to side effects not stated in this leaflet.  
You can register any side effects directly with the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: [www.bfarm.de](http://www.bfarm.de). By reporting any side effects, you can make a contribution towards more information being available on the safety of this medicinal product.

#### **5. HOW SHOULD MILK THISTLE CAPSULES BE STORED?**

Keep all medicines out of the reach and sight of children.

Do not take the medicinal product if the "use by" date on the box or blister pack has expired. The use by date relates to the last day of the month in question.

**Storage information:** Do not store above 25 °C.

#### **6. Additional information**

##### **Contents of Milk Thistle Capsules:**

The active substance is Milk Thistle Dry Fruit Extract

##### **1 soft capsule contains:**

200 mg dry extract of part-oiled milk thistle fruit (30-40:1)

Extraction agent: Ethanol 96 % (V/V).

**Other ingredients:** Maltodextrin, Highly Dispersed Silicon Dioxide, Phospholipids from Soya Beans, Refined Soya Bean Oil (Ph.Eur.), Refined Coconut Fat, Refined Palm Kernel Oil, Yellow Wax, Butter Fat (from cow's milk), Gelatine, Glycerol, Sorbitol Solution 70% (non-crystallising) (Ph.Eur.), Quinoline Yellow (E 104), Titanium Dioxide (E 171), Iron (III) Hydroxide Oxide (E 172), Purified Water.

The medicinal product contains less than 0.1 CE.

One soft capsule contains 23.48 mg sorbitol (corresponds with 5.87 mg fructose).

**Packet sizes available:** Original packet with 90 soft capsules.

**This information leaflet was last updated in March 2022.**

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For risks and side effects please read the information leaflet and consult your doctor or pharmacist.