

Package leaflet: Information for the user

Carsil 22.5 mg coated tablets Silymarin

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

Always use this 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 your 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. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Carsil is and what it is used for
2. What you need to know before you use Carsil
3. How to use Carsil
4. Possible side effects
5. How to store Carsil
6. Contents of the pack and other information

1. What Carsil is and what it is used for

Carsil coated tablets are a medicine containing the active substance silymarin, an agent derived from milk thistle seeds. Silymarin activates the synthesis of proteins and phospholipids in damaged hepatic cells, stabilises cell membranes, binds free radicals (antioxydative activity), thereby protecting hepatic cells from harmful effects.

Carsil is used in the supportive treatment of liver damage.

2. What you need to know before you use Carsil

Do not use Carsil:

- if you are allergic to silymarin or any of the other ingredients of this medicine (listed in section 6).
- if the patient is a child under 12 years of age, as there is insufficient clinical experience with administering the medicine to children.

Warnings and precautions

Talk to your doctor or pharmacist before using Carsil.

Ask your doctor for advice before using Carsil coated tablets if you have a disease related to hormonal disorders (e.g. uterine, ovarian, mammary gland or prostate tumour).

Carsil coated tablets are used in the supportive treatment of liver damage; thus, you must continue eating properly and avoid using alcohol during the treatment.

Other medicines and Carsil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Carsil coated tablets can weaken the efficiency of oestrogen replacement treatment, oral contraceptives and tamoxifen.

Carsil can increase the activity of medicines, such as diazepam, alprazolam, ketoconazole, lovastatin and viblastine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Talk to your doctor before using Carsil if you are pregnant or trying to have a baby. Your doctor will decide whether you can use Carsil.

If you are breast-feeding, your doctor will decide whether you can use Carsil.

Carsil can be used during pregnancy or breast-feeding only for medical indications and only if the benefits of administering the medicine to the mother outweigh the risk to the foetus.

Driving and using machines

Carsil has no effect on the ability to drive or use machines.

Carsil contains wheat starch

This medicine contains only very low levels of gluten (from wheat starch) and is very unlikely to cause problems if you have coeliac disease. One tablet contains no more than 3,95 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

Carsil contains lactose monohydrate

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Carsil contains sucrose as excipient

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Carsil contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E 216)

These agents can cause allergic reactions (that can be late phase reactions).

3. How to use Carsil

Always use this 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.

Carsil coated tablets are administered orally before a meal; the tablets are administered whole with a sufficient amount of liquid.

Adults and adolescents

In severe cases, the loading dose is 4 tablets 3 times per day; in milder cases and as maintenance treatment, 1–2 tablets 2–3 times per day.

The treatment should last for at least 3 months.

Children under the age of 12:

There is insufficient data on the administration of this medicine to children, due to which it is not recommended to children under the age of 12.

If you take more Carsil than you should

If you have taken a larger than recommended dose, talk to your doctor.

If you forget to take Carsil

If you have missed a dose, take it as soon as you can. If it is almost time for the next dose, continue as usual. Do not take a double dose to make up for a forgotten dose. Continue using the medicine as prescribed.

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

4. Possible side effects

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

Carsil is well tolerated. In very rare cases, allergic skin reactions can occur, such as pruritus and rashes or anaphylactic shock (severe allergic reaction causing breathing difficulties and dizziness). In rare cases, there have been reports of the exacerbation of existing vestibular disorders. In rare cases, side effects can include diarrhoea or nausea, vomiting and indigestion accompanied by flatulence (meteorism).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carsil

Store the medicine in the original package in order to protect from moisture. Do not store at a temperature higher than 25 °C.

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

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or 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

What Carsil contains

- The active substance is 40.9–56.3 mg of milk thistle dry extract (*Silybi mariani fructus extractum siccum*), corresponding to 22.5 mg of silymarin in the form of silibinin.
- The other ingredients are:

Tablet core: lactose monohydrate, wheat starch, povidone, microcrystalline cellulose, magnesium stearate, talc, mannitol (E421), crospovidone, polysorbate 80, sodium bicarbonate.

Tablet coating: cellulose acetate phthalate, diethyl phthalate, sucrose, gum acacia, gelatin, talc, titanium dioxide (E171), macrogol 6000, glycerol, black iron oxide (E172), red iron oxide (E172), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216).

What Carsil looks like and contents of the pack

Standard round coated tablets, brown, odourless.

10 coated tablets in a PVC/aluminium blister pack;

8 blisters packs (80 coated tablets) in a cardboard carton with the package leaflet.

Market Authorisation Holder and Manufacturer responsible for batch release

Sopharma AD
16 Iliensko Shosse
1220 Sofia
Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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