

PATIENT LEAFLET: INFORMATION FOR THE USER

CHONDROMEL, 400 mg capsules

Chondroitin Sulphate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Chondromel is and what it is used for
2. What you need to know before you take Chondromel
3. How to take Chondromel
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1. WHAT CHONDROMEL IS AND WHAT IT IS USED FOR

The name of your medicine is Chondromel, 400 mg Capsules and its active ingredient is chondroitin sulphate.

Chondromel is used to treat the symptoms of osteoarthritis.

2. BEFORE YOU TAKE CHONDROMEL

Do not use Chondromel:

- If you have previously suffered an allergic reaction to a medicine containing chondroitin sulphate.
- If you are allergic to any of the other ingredients in this medicine (listed in the section 6).
- If you are suffering from liver failure.

Take special care with Chondromel:

- If you are being treated for heart, liver or kidney problems
- If you are pregnant, planning to become pregnant or breast-feeding

This medicine contains 36.5 mg sodium (main component of cooking/table salt) in each capsule. This is equivalent to 1.8% of the recommended maximum daily dietary intake of sodium for an adult.

Taking other medicines

There are no reports of interactions between chondroitin and other medicines at normal doses. However, please let your doctor or pharmacist know if you are taking any medicines that affect blood clotting, for instance aspirin, dipyridamole, clopidogrel, ditazole, triflusal and ticlopidine.

Pregnancy, breast-feeding and fertility

There is no information on the use of Chondromel during pregnancy or breast-feeding; therefore the product is not recommended in these cases. However, 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.

Driving and using machines

There is no evidence that Chondromel interferes with the ability to drive vehicles or operate machinery.

3. HOW TO TAKE CHONDROMEL

You should take your medicine as directed by your doctor. The pharmacist's label should tell you how much to take and how often. If it does not or you are not sure, ask your doctor or pharmacist.

Adults and the elderly:

The usual daily dose is 800 mg/day as a single dose (2 capsules) for 3 months. For symptoms of severe inflammation, the recommended starting dose is 1200 mg/day as a single dose (3 capsules at a time) or divided dose (1 capsule 3 times a day) for 4-6 weeks, followed by 800 mg for up to 3 months.

Treatment with Chondromel can be repeated as follows: Chondromel can be taken for three months continuously, however, this must be followed by a two month treatment-free period before resuming treatment. You can take Chondromel capsules with or without food. However, if you suffer from gastric problems you are recommended to take them with food. The capsules must be swallowed, not chewed, with sufficient fluid.

Do not take more than 1200 mg of chondroitin sulfate per day.

Use in children and adolescents:

The use of chondroitin sulphate has not been studied in children and it should therefore not be used in persons under the age of 18 years.

Kidney failure:

Chondromel should be used with caution and only under medical supervision by patients suffering from kidney failure.

Liver failure:

Chondromel is not recommended for use by patients suffering from liver failure.

If you take more capsules than you should:

If you accidentally take too many capsules you should contact your doctor or nearest hospital casualty department immediately.

If you forget to take your medicine:

If you forget to take a capsule take it as soon as you remember, then carry on as before.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking Chondromel capsules and tell your doctor immediately if:

- You have an allergic reaction such as a skin rash and swelling of the face, wheezing or difficulty breathing.
- You have heart or kidney problems and you experience swelling and/or water retention while taking the capsules.

Rare side effects, which affect less than 1 in 1,000 people include:

- Gastrointestinal disorder
- Stomach ache
- Nausea
- Diarrhoea
- Redness of the skin
- Rash
- Rash characterised by a flat, red area on the skin that is covered with small raised bumps

Very rare side effects which affect less than 1 in 10,000 people include

- Hives
- Eczema
- Itch
- Swelling

These symptoms are usually mild and disappear quickly.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE CHONDROMEL

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

Do not use the Chondromel capsules after the expiry date which is stated on the blister strip and carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

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. CONTENT OF THE PACK AND OTHER INFORMATION

What Chondromel contains

The active substance is chondroitin sulfate. Each capsule contains chondroitin sulfate sodium salt equivalent to 400 mg chondroitin sulfate.

The capsules also contain magnesium stearate. The capsule shell contains gelatin, quinoline yellow (E104) and indigo carmine (E132).

What Chondromel looks like and content of the pack

Chondromel capsules have a blue-green body and a light blue cap.

The pack may contain 60 or 180 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

IBSA Farmaceutici Italia S.r.l., Via Martiri di Cefalonia 2 – 26900 Lodi (Italy).

This leaflet was last revised in