

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glukosamin MIP 400 mg film coated tablets

Glucosamine

Read all of this leaflet carefully because it contains important information for you.

Certain packages of this medicine are available without prescription. However, you still need to take Glukosamin MIP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 1 month.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Glukosamin MIP is and what it is used for
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1. What Glukosamin MIP is and what it is used for

Glukosamin MIP belongs to the group of medicines called other non-steroidal anti-inflammatory and anti-rheumatic agents (other NSAIDs).

Glukosamin MIP is used for the relief of symptoms in mild to moderate osteoarthritis.

2. Before you take Glukosamin MIP

Do not take Glukosamin MIP

- if you are allergic (hypersensitive) to glucosamine or any of the other ingredients of Glukosamin MIP (see point 6, further information).
- if you are allergic (hypersensitive) to shellfish, since glucosamine is manufactured from shellfish

Take special care with Glukosamin MIP

Please take special care and tell your doctor:

- If you suffer from impaired glucose tolerance. More frequent controls of your blood glucose levels may be necessary when starting treatment with glucosamine.
- If you have kidney or liver dysfunction, dose recommendations cannot be given, since no studies have been performed in such patients.
- If you have a known risk factor for heart or vascular disease. This special care is necessary since too high cholesterol levels have been observed in a few cases in patients.
- If you suffer from asthma. When starting on glucosamine, you should be aware of potential worsening of symptoms

You should not use Glukosamin MIP if you are under the age of 18 years.

You should not use Glukosamin MIP longer than 1 month without consulting your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should take special caution if you combine Glukosamin MIP with other medicines, especially blood thinners like warfarin.

Please contact your doctor for medical advice.

Taking Glukosamin MIP with food and drink

You can take the tablets with or without food

Pregnancy and breast-feeding

Pregnant or breastfeeding women should not use Glukosamin MIP, since experience during pregnancy and during lactation is not sufficient.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you experience dizziness or drowsiness from the tablets you should not be driving or operating machinery. No studies on the effect on the ability to drive and use machines have been performed.

3. How to take Glukosamin MIP

Follow these instructions unless your doctor gave you different advice. You should check with your doctor or pharmacist if you are not sure.

The usual starting dose is one tablet three times a day. The maximum daily dose is 3 tablets. Alternatively, the total daily dose may be taken all together at the same time. The lowest effective dose should be used. The tablets should be swallowed with some liquid (e.g. 1 glass of water).

Therapy duration

Glucosamine is not specifically prescribed for the treatment of acute painful symptoms. Therefore it might take several weeks and in some cases even longer until you experience relief of symptoms (especially pain relief). If no relief of symptoms is experienced after 2-3-months, continued treatment with glucosamine should be re-evaluated.

Glukosamin MIP should not be used longer than 1 month without consulting your doctor.

If you take more Glukosamin MIP than you should

If you have taken more Glukosamin MIP than you should, please contact your doctor or the hospital.

If children have been taking medicine by accident, please contact your doctor or the hospital. They can give you an opinion of the risk and advice on action to be taken.

If you forget to take Glukosamin MIP

Do not take a double dose to make up for a forgotten dose. Continue the therapy as recommended.

If you stop taking Glucosamin MIP

Your symptoms may reoccur.

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

4. Possible side effects

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

The following side effects have been reported.

Common (fewer than 1 of 10 patients but more than 1 of 100 patients):

Headache, tiredness, indigestion, diarrhoea, abdominal pain, constipation, sick feeling.

Uncommon (fewer than 1 of 100 patients but more than 1 of 1000 patients):

Rash, itching, flushing.

Also the following side effects have been reported in the post-marketing experience of glucosamine products in general:

Swelling, hives, dizziness, asthma or worsening of asthma, blood glucose control worsening in patients with diabetes.

Stop taking Glukosamin MIP and immediately contact your doctor if you experience the following symptoms (angioedema):

- swollen face, tongue or throat
- difficulty in swallowing
- hives and difficulty breathing

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Glukosamin MIP

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use Glukosamin MIP after the expiry date which is stated on the carton/blister.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Glukosamin MIP contains

- The active substance is glucosamine.
The tablets contain a glucosamine hydrochloride-magnesiumsulphate complex (2:1).
1 film coated tablet corresponds to 400 mg of glucosamine and corresponds to 509 mg of glucosamine sulphate.
- The other ingredients are microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, talc, basic butylated methacrylate copolymer (Eudragit E), macrogol 6000, titanium dioxide (E 171).

What Glukosamin MIP looks like and contents of the pack

Glucosamin MIP is a white to slightly yellow, oblong film-coated tablet with a score line.

Packs-sizes of 10, 20, 30, 50, 100, 300 film-coated tablets. Packages with 300 tablets are only available on prescription.

Not all sizes may be marketed.

Marketing authorisation holder

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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Perigona
Finland	Perigona
Norway	Perigona
Sweden	Glukosamin MIP

This leaflet was last approved on 6 May, 2009