

Package Leaflet: Information for the User

Glucosamine sulfate 750 mg Film-Coated Tablets

Glucosamine Sulfate

Read all of this leaflet carefully before you 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 or pharmacist.
- 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
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What is in this leaflet:

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

1. What Glucosamine sulfate is and what it is used for

Glucosamine sulfate belongs to a group of medicines called other anti-inflammatory and anti-rheumatic agents, non steroids.

Glucosamine sulfate is used for the relief of symptoms of mild to moderate osteoarthritis of the knee.

Osteoarthritis is a type of joint degeneration that generates symptoms such as stiffness (after sleep or long rest) and pain at motion (e.g. when climbing the stairs or walking along uneven surfaces).

2. What you need to know before you take Glucosamine sulfate

DO NOT TAKE Glucosamine sulfate

- If you are allergic to:
 - Glucosamine or to any of the other ingredients of Glucosamine sulfate® (listed in section 6)
 - Shellfish, since Glucosamine sulfate is manufactured from shellfish.
 - Peanut or soya, since <Invented Name> contains soya lecithin.

Warnings and precautions

TAKE SPECIAL CARE with Glucosamine sulfate if you

- Suffer from impaired glucose tolerance. More frequent controls of your blood glucose levels may be necessary when starting treatment with Glucosamine sulfate

- Have kidney or liver dysfunction, since no studies have been performed in such patients dose recommendations cannot be given.
- Have a known risk factor for heart (cardiovascular) disease, since high cholesterol (hypercholesterolemia) has been observed in a few cases in patients treated with Glucosamine sulfate.
- Suffer with asthma. When starting on Glucosamine sulfate, you should be aware of potential worsening of symptoms.
- If you have joint swelling, warmth and redness, joint painfulness, persistent joint stiffness, pain at rest, pain in more than one joint, increased body temperature and decrease in body weight because they can be symptoms of more serious diseases such as rheumatoid arthritis, systemic lupus, gout, tumours.

Consult a doctor before using Glucosamine sulfate if any of the above mentioned applies to you.

Other medicines and Glucosamine sulfate

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

Caution should be exercised if Glucosamine sulfate has to be combined with other medicines, especially with:

- Warfarin (a medicine used to thin the blood) or similar type of products (anticoagulants used to prevent blood-clotting). The effect of the anticoagulant may be intensified in association with glucosamine. Patients treated with such combinations should therefore be monitored extra carefully when initiating or ending glucosamine therapy.
- Medicines for diabetes, your doctor may wish to monitor your blood sugar levels closely while you are taking Glucosamine sulfate
- Tetracycline (an antibiotic effective against a wide range of bacterial infections).

Please contact your doctor or pharmacist for medical advice before using Glucosamine sulfate if you use any of the above mentioned medicines.

Glucosamine sulfate with food and drink

You can take Glucosamine sulfate with or without food.

Pregnancy, breast-feeding and fertility

Glucosamine sulfate should not be used during pregnancy. The use of Glucosamine sulfate during breast-feeding is not recommended.

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

No studies on the effects on the ability to drive and use machines have been performed. If you experience dizziness or drowsiness from Glucosamine sulfate, you should not drive or operate machinery.

Important information about some of the ingredients of Glucosamine sulfate

This medicinal product contains 76 mg sodium per tablet. This should be taken into consideration by patients on a controlled sodium diet. Glucosamine sulfate contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Glucosamine sulfate contains soya lecithin. Do not use this product if you are allergic to soya or peanuts.

3. How to take Glucosamine sulfate

Always take Glucosamine sulfate exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

One Glucosamine sulfate tablet should be taken twice daily or two Glucosamine sulfate tablets to be taken once daily. The tablets should be swallowed whole with water.

Glucosamine sulfate is not indicated for the treatment of acute painful symptoms (rapid onset of brief severe pain). Relief of symptoms (especially pain relief) may not be experienced until after several weeks of treatment and in some cases even longer. If no relief of symptoms is experienced after 2-3 months, continued treatment with Glucosamine sulfate should be re-evaluated and medical advice sought.

Children and adolescents

Glucosamine sulfate is not recommended for use in children and adolescents below the age of 18, due to lack of data on safety and efficacy.

Elderly

No dosage adjustment is required when treating otherwise healthy elderly patients, however your doctor will decide your dose.

Patients with impaired renal and/or liver function

No dose recommendations can be given, since no studies have been performed.

If you take more Glucosamine sulfate than you should

If you have taken large quantities you must consult your doctor or a hospital.

In case of an overdose you may experience symptoms such as:

- headache
- dizziness
- disorientation
- joint pain
- feeling sick (nausea) or being sick (vomiting)
- diarrhoea or constipation.

If you forget to take Glucosamine sulfate

Do not take a double dose to make up for a forgotten dose.

If you stop using Glucosamine sulfate

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, Glucosamine sulfate can cause side effects, although not everyone gets them.

You should stop taking Glucosamine sulfate and see your doctor immediately if you experience symptoms such as: swollen face, tongue and/or pharynx and/or difficulty to swallow or hives together with difficulties to breathe (angioedema).

The following side effects have been reported:

Common side-effects (in less than 1 in 10 patients but in more than 1 out of 100 patients treated)

- Headache
- Tiredness
- Nausea
- Abdominal pain
- Indigestion
- Diarrhoea
- Constipation
- Wind (flatulence)

Uncommon side-effects (in less than 1 in 100 patients but more than 1 in 1000 patients treated)

- Rash
- Itching
- Flushing

Unknown frequency (cannot be estimated from the available data)

- Allergic reaction
- Visual disturbance
- Hair loss (alopecia)
- Dizziness
- Swelling of the feet or ankles
- Vomiting
- Diabetes mellitus inadequate control
- Asthma or aggravation of pre-existing asthma
- Increased liver enzymes (hepatic enzyme elevation)
- Yellow discoloration of the skin (jaundice)

Elevated cholesterol levels have been also reported. It is not possible to determine whether these events were directly related to Glucosamine sulfate

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Glucosamine sulfate

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

Do not use Glucosamine sulfate after the expiry date stated on the label and carton after EXP:. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

After first opening of the tablet container the product should be used within 6 months.

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 Glucosamine sulfate contains

The active substance is glucosamine sulfate. Each tablet contains 942 mg of glucosamine sulfate sodium chloride (equivalent to 750 mg of glucosamine sulfate) or 589 mg glucosamine.

The other ingredients are

Tablet: microcrystalline cellulose 101, microcrystalline cellulose 102, lactose monohydrate, pregelatinised maize starch, crospovidone, stearic acid

Coating: poly(vinyl) alcohol, titanium dioxide (E171), talc (E553b), lecithin soya (E322), macrogol 3350.

What Glucosamine sulfate looks like and contents of the pack

Glucosamine sulfate 750 mg tablets are off-white, oblong shaped, film-coated tablets, 8x19mm.

The tablets are available in two types of packaging:

Cartons containing PVdC coated PVC/Al blisters.

Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180, 336, 360 film-coated tablets.
or

Cartons containing HDPE containers fitted with a tamper-evident HDPE screw cap.

Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180, 336, 360 film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder

FMC Pharma Ltd.

Unit 622, Northern extension, Co. Waterford
Ireland

Manufacturers

Chanelle Medical, Loughrea, Co.Galway, Ireland.

Walmart a.s, Oldrichovice 44, 739 61 Trinec, Czech Republic.

Millmount Healthcare Ltd. Block 7, CityNorth Business Campus, Stamullen, County Meath
Ireland

mibe GmbH Arzneimittel, Münchener Straße 15, 06796 Brehna, Germany

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

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| Ireland: | Glucosamine sulfate 750 mg Film-coated tablets |
| Germany: | Glusadon 589 mg Filmtabletten |

This leaflet was last approved in: May 2016