

Package Leaflet: Information for the User

Glusamin 1500 mg Film-Coated Tablets

Glucosamine Sulfate

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

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

1. What Glusamin is and what it is used for

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

Glusamin 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 Glusamin

DO NOT TAKE Glusamin

- If you are allergic (hypersensitive) to:
 - Glucosamine or to any of the other ingredients of Glusamin (see Section 6 “Further Information”)
 - Shellfish, since Glusamin is manufactured from shellfish.

Warnings and precautions

TAKE SPECIAL CARE with Glusamin if you

- Suffer from impaired glucose tolerance. More frequent controls of your blood glucose levels may be necessary when starting treatment with Glusamin
- 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 Glusamin.
- Suffer with asthma. When starting on Glusamin, 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 Glusamin if any of the above mentioned applies to you.

Other medicines and Glusamin

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

Caution should be exercised if Glusamin 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 Glusamin
- Tetracycline (an antibiotic effective against a wide range of bacterial infections).

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

Glusamin with food and drink

You can take Glusamin with or without food.

Pregnancy and breast-feeding

Glusamin should not be used during pregnancy. The use of Glusamin during breast-feeding is not recommended. Ask your doctor or pharmacist for advice before taking any 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 Glusamin, you should not drive or operate machinery.

Important information about some of the ingredients of Glusamin

This medicinal product contains 152 mg sodium per tablet. This should be taken into consideration by patients on a controlled sodium diet. Glusamin 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. Glusamin contains soya lecithin. Do not use this product if you are allergic to soya or peanuts.

3. How to take Glusamin

Always take Glusamin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

One Glusamin tablet should be taken once daily. The tablets should be swallowed whole with water.

Glusamin 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 Glusamin should be re-evaluated and medical advice sought.

Use in children and adolescents

Glusamin 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 Glusamin 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 Glusamin

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

If you stop using Glusamin

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, Glusamin can cause side effects, although not everyone gets them.

You should stop taking Glusamin 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

- 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 Glusamin

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.

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
 Pharmacovigilance Section
 Irish Medicines Board
 Kevin O'Malley House
 Earlsfort Centre
 Earlsfort Terrace
 Dublin 2
 Tel: +353 1 6764971
 Fax: +353 1 6762517
 Website: www.imb.ie
 e-mail: imbpharmacovigilance@imb.ie

5. How to store Glusamin

Keep out of the reach and sight of children.

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

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

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

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. Contents of the pack and other information

What Glusamin contains

The active substance is ~~<Invented Name>~~ glucosamine sulfate. Each tablet contains 1884 mg of glucosamine sulfate sodium chloride (equivalent to 1500 mg of glucosamine sulfate) or 1178mg glucosamine.

The other ingredients are

Tablet: Microcrystalline cellulose 101, Microcrystalline cellulose 102, lactose monohydrate, pregelatinised maize starch, croscopovidone, stearic acid,

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

hat Glusamin looks like and contents of the pack

Glusamin 1500 mg tablets are off-white, oblong, film-coated tablets.

The tablets are available in two types of packaging.

Cartons containing PVdC coated PVC/Al blisters

Pack Size: 7,10,14,20,21,28,30, 56,60,84,90, 168,180 film-coated tablets

or

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

Pack Size: 7,10,14,20,21,28,30, 56,60,84,90, 168,180 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

| This leaflet was last revised in: ~~Sept~~ June 20134

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