

Package leaflet: Information for the user

Glucosamina Glusina 1500 mg Powder for oral solution Glucosamine Sulfate

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

Take this medicine exactly as described in this leaflet, or as indicated by your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

If you need clarification or advice, consult your pharmacist.

If you experience any undesirable effects, including possible undesirable effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

If you don't feel better or get worse, you need to see a doctor.

What this leaflet contains:

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

1. What Glucosamina Glusina is and what it is used for

The medicine has as active substance Glucosamine Sulfate in the form of powder for oral solution and is presented in sachets dosed with 1500 mg of Glucosamine Sulfate for oral administration.

It is used in the treatment of the symptoms of osteoarthritis, that is, pain and limitation of function.

Arthritis is characterized by a degenerative process of the articular cartilage, in which it is being destroyed. Glucosamine Sulfate is a constituent of cartilage that is necessary for its regeneration and that can stimulate cartilage-forming cells, contributing to delay or even stop the degenerative process.

2. What you need to know before taking Glucosamina Glusina

Do not take Glucosamina Glusina

- if you are allergic to glucosamine sulphate or any of the other ingredients of this medicine (listed in section 6).

- The powder for oral solution contains aspartame and is therefore contraindicated in patients with phenylketonuria.

Warnings and precautions

Talk to your doctor or pharmacist before taking Glucosamina Glusina.

Glucosamine is a natural constituent of the body and is therefore extremely well tolerated. Patients with glucose intolerance need to be monitored and blood glucose values need monitoring, especially at the start of treatment. There may, however, be hypersensitivity reactions in people allergic to shellfish once the active substance is extracted from shellfish.

Safety and efficacy have not yet been established in children and adolescents under 18 years of age, which is why administration in these patients should be avoided.

Children and adolescents

Safety and efficacy have not been established in children and adolescents under 18 years of age, so no dose recommendations can be made.

Other Medicines and Glucosamina Glusina

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

Glucosamine sulfate may favor the gastrointestinal absorption of tetracyclines and may reduce that of penicillins or chloramphenicol when administered simultaneously orally.

Caution should be exercised if Glucosamina Glusina has to be combined with other medicines, especially with:

– Some types of medicines used to prevent blood clotting (e.g. warfarin, dicumarol, phenprocoumon, acenocoumarol and fluindione). The effect of these medicines may be stronger when used with glucosamine. Therefore, patients treated with these combinations should be monitored with additional caution when initiating or terminating glucosamine therapy.

There is no impediment to the concomitant administration of analgesics or steroidal or non-steroidal anti-inflammatory drugs. On the contrary, glucosamine can be used as an adjuvant because it develops an anti-inflammatory, cyclooxygenase-independent therapeutic activity and, above all, because it can prevent joint damage caused by these drugs which, by virtue of their mechanism of action, lead to an enzymatic blockade of the synthesis of proteoglycans.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or plan to become pregnant, consult your doctor or pharmacist before taking this medicine.

As a precaution, the administration of medicinal products during pregnancy should only be done if necessary and under medical supervision, especially in the three first months.

As a precaution, the administration of drugs during lactation should only be done if necessary and under medical supervision.

Driving and using machines

If you are taking Glucosamina Glusina, there is no inconvenience in driving or using machines because this medicine does not affect your reflexes.

Contains aspartame a source of phenylalanine and may be harmful to patients with phenylketonuria.

Contains 151,099 mg of sodium per sachet. This information should be taken into account in patients with controlled sodium intake.

Contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact him or her before taking this medicine.

3. How to Take Glucosamine

Take this medicine exactly as indicated by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

You should take the contents of a sachet (dissolved in a glass with water) once a day, preferably with meals.

Use in children and adolescents

Safety and efficacy have not yet been established in children and adolescents under 18 years of age, so no dose recommendations can be given.

Use in renal and hepatic insufficiency

As no studies have been conducted in patients with renal and/or hepatic impairment, no dose recommendations can be given.

If you take more Glucosamina Glusina than you should

No cases of accidental or intentional overdose were observed. Based on the acute and chronic toxicity data in the animal, toxic symptoms are not to be expected, even after high overdoses.

However, if any episode of overdose occurs, symptomatic treatment should be performed, i.e. act in order to restore the hydroelectrolyte balance.

If you forget to take Glucosamina Glusina

Continue treatment without change.

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

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

4. Possible undesirable effects

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

Generally speaking, Glucosamina Glusina is well tolerated.

The most frequent undesirable effects are mild and transient, being more common those of a gastrointestinal nature (gastric pain and discomfort, meteorism, constipation and diarrhea).

The following list lists the possible undesirable effects taking into account their frequency:

Common ($>1/100$, $<1/10$):

Gastrointestinal diseases:

Gastric pain and discomfort

Meteorism

Constipation

Diarrhoea

Uncommon ($> 1/1000$, $<1/100$):

Skin and subcutaneous tissue disorders:

Skin rash with itching.

Erythema.

Rare ($> 1/10000$, $<1/1000$):

Respiratory, thoracic and mediastinal diseases:

Bronchial hyperreactivity

It is advisable to discontinue therapy in case of manifestation of pruritus, erythema or bronchial hyperreactivity.

Reporting of undesirable effects

If you experience any undesirable effects, including possible undesirable effects not listed in this leaflet, talk to your pharmacist. You can also report undesirable effects directly to Health Authorities. By reporting undesirable effects, you are helping to provide more information about the safety of this medicine.

5. How to store Glucosamina Glusina

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

Do not use Glucosamina Glusina after the expiry date which is stated on the sachets after EXP. The expiry date refers to the last day of that month.

Store below 25°C

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

Medicines should not be disposed of in plumbing or household waste.

Ask your pharmacist how to dispose of medicines you no longer need. These measures will help to protect the environment.

6. Contents of the pack and other information

What Glucosamina Glusina contains

The active substance is glucosamine sulfate.

The other ingredients are aspartame, sorbitol, citric acid and macrogol 4000.

What Glucosamina Glusina looks like and contents of the pack

Packs of 7, 20, 30 and 60 sachets of powder for oral solution

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

Avita LTD

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Manufacturer:

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