

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glucomed 625 mg tablets

Glucosamine

Note: grey-shaded text in PL is intended for OTC products only.

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 further questions, please 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.

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after <x> months.

In this leaflet:

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

1. What Glucomed is and what it is used for

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

Glucomed is used for the relief of symptoms in mild to moderate osteoarthritis of the knee.

2. What you need to know before you take Glucomed

Do not take Glucomed if you:

- are **allergic** to **glucosamine** or to **any of the other ingredients** of *this medicine (listed in section 6)*.
- are **allergic** (hypersensitive) to **shellfish**, since glucosamine is manufactured from shellfish.

Warnings and precautions

Glucosamine is not indicated for the treatment of acute painful symptoms.

Talk to your doctor or pharmacist before taking Glucomed if you:

- suffer from **impaired glucose tolerance**. More frequent controls of your blood glucose levels may be necessary when starting treatment with Glucomed.
- have a **known risk factor for cardiovascular (heart) disease**, since an abnormally high level of cholesterol in the blood has been observed in a few patients treated with Glucomed.
- suffer from **asthma**. When starting on Glucomed, you should be aware of potential worsening of symptoms.

Children and adolescents

Glucomed should not be used in children and adolescents below the age of 18 years.

Other medicines and Glucomed

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

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

- Some types of medicines used to prevent blood clotting (e.g. warfarin, dicoumarol, phenprocoumon, acenocoumarol and fluidione). The effect of these medicines may be stronger when used with glucosamine. Patients treated with such combinations should therefore be monitored extra carefully when initiating or ending glucosamine therapy.
- tetracyclines (antibacterials used against infections)

Please contact your doctor for medical advice.

Pregnancy, breast-feeding and fertility

Glucomed should not be used during pregnancy.

The use of Glucomed during breastfeeding 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 the tablets, you should not drive or operate machinery.

3. How to take Glucomed

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended starting dose is 2 tablets (1250 mg of glucosamine) once daily, taken orally.

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 Glucomed should be re-evaluated.

Relief of symptoms (especially pain relief) may not be experienced until after several weeks of treatment and in some cases even longer. Glucomed should not be used for a longer period than <x> month without contact with a doctor.

In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed.

For oral use.

The tablets should be swallowed together with some water or other suitable liquid. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

If you take more Glucomed than you should

If you have taken large quantities, you must consult your doctor or a hospital. Signs and symptoms of overdose with glucosamine might include headache, dizziness, confusion, joint pain, feeling sick, vomiting (being sick), diarrhoea or constipation. Stop taking glucosamine at signs of overdose.

If you forget to take Glucomed

Do not take a double dose to make up for a forgotten dose. If it is almost time for your next dose, skip the forgotten dose and carry on taking Glucomed as scheduled.

If you stop taking Glucomed

Please tell your doctor, a modification of the treatment of your symptoms might be required. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

You should stop taking Glucomed and immediately call emergency services or go to the hospital if you experience symptoms of angioedema, such as

- swollen face, tongue or throat
- difficulty to swallow
- hives and difficulties to breath

The following have been reported:

Common (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

Rash, itching, flushing.

Not known (frequency cannot be estimated from the available data): hives, swelling/swelling of ankles, legs and feet, dizziness, vomiting (being sick), blood glucose control worsened in patients with diabetes mellitus, hepatic enzyme elevation, jaundice.

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 Glucomed

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

Do not use this medicine after the expiry date which is stated on the blister/carton after {abbreviation used for expiry date}. The expiry date refers to the last day of that month. Do not store above 30°C.

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

Do not use this medicine if you notice any visible signs of deterioration.

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 to protect the environment.

6. Contents of the pack and other information

What Glucomed contains

- The active substance is glucosamine. Each tablet contains 750 mg glucosamine hydrochloride equivalent to 625 mg of glucosamine
- The other ingredients are microcrystalline cellulose, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose (L-HPC) and magnesium stearate.

What Glucomed looks like and content of the pack

Glucomed is a white to light beige, oval tablet of 10 mm x 18.75 mm marked with “G” on one side and a score line on the other side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC/PVDC-aluminium blisters packed in paper cartons.
Pack-sizes of 20, 40, 60 or 180 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Laboratoires Expanscience
1 place des Saisons – 92048 Paris La Défense Cedex, France

Manufacturer:

FAMAR ITALIA S.p.A., Via Zambelletti 25, 20021 Baranzate, Italy

Haupt Pharma Wülfig GmbH, Bethelner Landstr. 18, 31028 Gronau, Germany

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

Czech Republic Flexove

France	Flexea
Iceland	Glucomed
Poland	Flexove
Portugal	Glucomed
Slovakia	Glucomed
Sweden	Glucomed

This leaflet was last revised in: 2024-06-20

Detailed information on this medicine is available on the web site of {name of MS/Agency}