

OTC

Due to the different legal status in different countries certain OTC-information has been added to the PL. The OTC-information is marked in grey shadings, If it is not indicated for OTC the grey shaded parts will be deleted in the national version.

Package leaflet: Information for the user

Glufan 625 mg film coated tablets

glucosamine

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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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 one month.

What is in this leaflet

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

1. What Glufan is and what it is used for

Glucosamine is a natural substance produced from glucose (a sugar). Glucosamine is necessary for the body to produce larger molecules found for instance in joint fluid and cartilage.

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

2. What you need to know before you take Glufan

Do not take Glufan

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

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- if you are allergic to shellfish, as the active ingredient, glucosamine, is extracted from shellfish.

Warnings and precautions

Talk to your doctor or pharmacist before taking Glufan

- if you have diabetes you should ask your doctor before taking Glufan, and your blood sugar levels may need to be checked more often at the start of treatment.
- if you suffer from asthma, you should be aware of potential worsening of symptoms when starting treatment with Glufan.

Stop taking Glufan and contact a doctor immediately if you experience any of the following symptoms (angio-oedema):

- swelling of the face, tongue or throat
- difficulty swallowing
- hives and trouble breathing.

Other medicines and Glufan

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

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.

Pregnancy and breast-feeding

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.

You should not use Glufan if you are pregnant or breast-feeding.

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

Driving and using machines

Glufan does not affect the ability to drive or use machines, but if Glufan make you tired or give you a headache you should not drive or use machines.

Glufan contains sunset yellow FCF aluminium lake (E 110)

This medicinal product may cause allergic reactions because it contains sunset yellow FCF aluminium lake (E 110).

3. How to take Glufan

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

Your doctor has decided on a daily dose based on your individual needs.

The recommended starting dose is 1 tablet twice daily. After the symptoms have been relieved the dose may be decreased to 1 tablet daily. The tablets should be swallowed with liquid.

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The recommended starting dose is 1 tablet twice daily. After the symptoms have been relieved the dose may be decreased to 1 tablet daily.

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

Use in children and adolescents

Glufan should not be given to children or adolescents under the age of 18 years.

The tablets should be swallowed with liquid.

If you take more Glufan than you should

Signs and symptoms of overdose with glucosamine may include headache, dizziness, disorientation, joint pain, nausea, vomiting, diarrhoea or constipation. In case of overdose, treatment with Glufan should be discontinued.

If you forget to take Glufan

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

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

4. Possible side effects

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

The following side effects have been reported:

Common (may affect up to 1 in 10 people): headache, drowsiness, upper abdominal discomfort.

Uncommon (may affect up to 1 in 100 people): rash, itching, redness of the skin.

Not known (frequency cannot be estimated from the available data): dizziness, asthma or worsening of asthma, stomach ache, diarrhoea, nausea/vomiting, swelling of the face, tongue or throat (angio-oedema, see Warning and precautions), hives, worsening of blood glucose control in patients with diabetes mellitus, oedema in e.g. ankles, legs and feet, liver impairment (increased enzymes and 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 Glufan

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Keep this medicine out of the sight and reach of children.
Do not store above 30°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the package after “EXP.”. The expiry date refers to the last day of that month.

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 Glufan contains**

- The active substance is glucosamine hydrochloride corresponding to 625 mg glucosamine (equivalent to 750 mg of glucosamine hydrochloride).
- The other ingredients (excipients) are:
Tablet core: povidone, calcium phosphate, microcrystalline cellulose, crospovidone and magnesium stearate.
- *Coating:* polyvinyl alcohol, talc, lecithin, macrogol, titanium dioxide (E 171), sunset yellow FCF aluminium lake (E 110), quinoline yellow (E 104), yellow iron oxide (E 172).

What Glufan looks like and contents of the pack

The tablets are oval and yellow.

Glufan comes in 4 different package sizes, 20 tablets (prescription free) 60 tablets (prescription free), 90 tablets (prescription) and 180 tablets (prescription).

Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

<To be completed nationally>

Manufacturer

<To be completed nationally>

This leaflet was last revised in 15-April-2021

<To be completed nationally>