Package leaflet: Information for the user

Gluart 1500 mg Film-coated tablets

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 your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- If you need clarification or advice, please consult your pharmacist.
- If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.
- If you don't feel better or if it gets worse, you need to see a doctor.

What's in this leaflet:

1. What Gluart is and what it is used for

Gluart belongs to a group of medicines called other non-steroidal anti-inflammatory and antirheumatic agents.
Gluart is indicated 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 sleeping or a long rest) and pain when moving (for example, when climbing stairs or walking along uneven surfaces).

2. What you need to know before you take Gluart

Do not take Gluart:
- If you are allergic (hypersensitive) to glucosamine or any of the other ingredients of this medicine (listed in section 6)
- If you are allergic (hypersensitive) to shellfish, as Gluart is obtained from shellfish.

Warnings and precautions

Talk to your doctor or pharmacist before taking Gluart if:
- Has reduced tolerance to glucose. More frequent checks of your blood glucose levels may be required at the start of treatment with Gluart
- Have renal or hepatic impairment, as no studies have been conducted in such patients, no dosage recommendations can be made.
- Has a known risk factor for heart (cardiovascular) disease, as high cholesterol (hypercholesterolaemia) has been observed in some cases in patients treated with Gluart.
- Suffers from asthma. When starting treatment with Gluart, you should be informed of the possibility of worsening symptoms.

- If you have swelling of the joints, feeling of heat and redness, joint pain, persistent stiffness of the joints, pain at rest, pain in more than one joint, increase in body temperature and loss of body weight because these can be symptoms of more serious diseases such as rheumatoid arthritis, systemic lupus, gout, tumors.
Consult a doctor before taking Gluart if any of the above apply to you.

Other medicines and Gluart

Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines.
Caution should be exercised if Gluart has to be combined with other medicinal products, particularly with:
- Warfarin (a medicine used to make the blood more fluid) or similar medicines (anticoagulants used to prevent blood clots). The anticoagulant effect may be intensified in combination with glucosamine. Therefore, patients treated with such combinations should be monitored with extra caution when starting or ending glucosamine treatment.
- Diabetes medications; your doctor may want to closely monitor your blood sugar levels while you are taking Gluart
- Tetracycline (an antibiotic effective against a wide range of bacterial infections).
Talk to your doctor or pharmacist before taking Gluart if you are taking any of the medicines mentioned above.

Gluart with food and drinks
You can take Gluart with or without food.

Pregnancy and breastfeeding
Gluart should not be used during pregnancy. The use of Gluart during the lactation period is not recommended.
If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
No studies have been carried out on the effects on the ability to drive and use machines. If you experience dizziness or drowsiness due to Gluart, do not drive or operate machinery.

Gluart contains sodium, lactose and soy lecithin
This medicine contains 152 mg of sodium (the main component of table salt) in each tablet. This is equivalent to 7.6% of the maximum recommended daily sodium intake in the diet for an adult.

Gluart contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Gluart contains soy lecithin. If you are allergic to peanuts or soybeans, do not use this medicine.

3. How to take Gluart
Take this medication exactly as directed by your doctor. Check with your doctor or pharmacist if you are not sure.

Take one tablet of Gluart a day. The tablets should be swallowed whole with water.

Gluart is not indicated for the treatment of symptoms of acute pain (rapid onset of brief severe pain). Symptom relief (especially pain relief) may not be seen until a few

weeks of treatment have passed, and in some cases it may take longer. If there is no relief of symptoms after 2-3 months, long-term treatment with Gluart should be re-evaluated and medical advice sought.

Use in children and adolescents
Gluart is not recommended for use in children and adolescents below the age of 18 years due to a lack of data on safety and efficacy.

Elderly
No dose adjustment is necessary during treatment of healthy elderly patients, however your doctor will decide your dose.

Patients with impaired renal and/or hepatic function
Since no studies have been conducted, no dosage recommendations can be made.

If you take more Gluart than you should
If you have taken excessive amounts, you should consult your doctor or a hospital.
In case of overdose, you may experience symptoms such as:
headache
Dizziness
disorientation
joint pain
feeling unwell (nausea) or feeling unwell (vomiting)
diarrhoea or constipation.

If you forget to take Gluart
Do not take a double dose to make up for a forgotten dose.

If you stop taking Gluart
Your symptoms may come back.

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.

You should stop taking Gluart and see your doctor immediately if you experience symptoms such as: swelling of the face, tongue and/or pharynx and/or difficulty swallowing or hives along with difficulty breathing (angioedema).

The following undesirable effects have been reported:
Common undesirable effects (in less than 1 in 10 patients but in more than 1 in 100 patients treated)
- Headache
-Tiredness
-Nausea
- Abdominal pain
-Indigestion
-Diarrhoea
-Constipation
- Gas (flatulence)

Uncommon undesirable effects (in less than 1 in 100 patients but in more than 1 in 1000 patients treated)
-Rash
-Itch
-Hot flashes

Frequency not known
- Allergic reaction
- Visual disturbances
- Hair loss (alopecia)
-Dizziness
- Swelling of the feet or ankles
-Vomiting
- Inadequate control of diabetes mellitus
- Asthma or worsening of pre-existing asthma
- Increased liver enzymes (elevation of liver enzymes)
- Yellow discoloration of the skin (jaundice)

High levels of cholesterol in the blood have also been reported. It is not possible to determine whether these events are directly related to Gluart.

Reporting of undesirable effects
If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Website: http://www.infarmed.pt/web/infarmed/submissaoram
(preferably)
or through the following contacts:
Directorate of Drug Risk Management
Parque da Saúde de Lisboa, Av. Brazil 53
1749-004 Lisboa
Tel: +351 21 798 73 73
Drug Line: 800222444 (free of charge)
Email: farmacovigilancia@infarmed.pt

5. How to store Gluart

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

The medicinal product does not require special storage temperature conditions.
Store in the original carton to protect from moisture.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Package contents and other information

What Gluart contains

The active substance is glucosamine sulphate. Each tablet contains 1884 mg glucosamine sulphate sodium chloride (equivalent to 1500 mg glucosamine sulphate) or 1178 mg glucosamine.

The other components are
Tablet: Microcrystalline cellulose 101, Microcrystalline cellulose 102, lactose monohydrate, pre-gelled corn starch, crospovidone, stearic acid.
Coating: partially hydrolyzed polyvinyl alcohol, titanium dioxide (E171), talc (E553b), soy lecithin (E322), macrogol 3350.

What Gluart looks like and contents of the pack
Gluart 1500 mg tablets are film-coated, off-white, oblong tablets.

Packs containing PVC-Al coated PVDC blister packs.
Pack sizes: 14, 15, 56 and 60 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer:

Marketing Authorization Holder

Baldacci-Portugal, S.A.
Rua Cândido de Figueiredo, nº84 B
1549-005 Lisboa
Portugal

Manufacturer
Pharmex Advanced Laboratories S.L.
Road A-431 Km 19,
14720 Almodovar del Rio,
Cordoba
Spain

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