

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flexove 625 mg tablets

Glucosamine

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

In this leaflet:

1. What Flexove is and what it is used for
2. What you need to know before you take Flexove
3. How to take Flexove
4. Possible side effects
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1. What Flexove is and what it is used for

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

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

2. What you need to know before you take Flexove

Do not take Flexove if you:

- are **allergic** to **glucosamine** or to **any of the other ingredients** of Flexove 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 Flexove

- suffer from **impaired glucose tolerance**. More frequent controls of your blood glucose levels may be necessary when starting treatment with Flexove.
- 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 Flexove.

- suffer from **asthma**. When starting on Flexove, you should be aware of potential worsening of symptoms.

Children and adolescents

- Flexove should not be used in children and adolescents below the age of 18.

Other medicines and Flexove

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

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

- warfarin (an anticoagulant used to prevent blood clotting)
- tetracycline (antibacterials used against infections)

Increased effect of coumarin anticoagulants (e.g. warfarin) during concomitant treatment with glucosamine has been reported. Patients treated with such combinations should therefore be monitored extra carefully when initiating or ending glucosamine therapy.

Please contact your doctor for medical advice.

Pregnancy, breast-feeding and fertility

Flexove should not be used during pregnancy.

The use of Flexove during breast-feeding 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 Flexove

Always take this medicine exactly 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 Flexove should be re-evaluated.

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 not intended for breaking the tablet.

If you take more Flexove 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 Flexove

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 Flexove as scheduled.

If you stop taking Flexove

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. The following have been reported:

You should stop taking Flexove 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

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

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

Uncommon (may affects 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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flexove

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 or tablet container after {abbreviation used for expiry date}. The expiry date refers to the last day of that month.

Do not store above 30°C.

Bottle:

Keep the bottle tightly closed. Store in the original package in order to protect from moisture.

Blister:

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 Flexove 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 Flexove looks like and content of the pack

Flexove is a white to light beige, oval tablet of 10x18,75 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.

HDPE tablet container with a silica gel desiccant in Tyvek bags.

Pack-sizes of 60 or 180 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Laboratoires Expanscience

10 avenue de l’Arche, 92419 Courbevoie Cedex, France

Manufacturers:

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

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

Austria	Flexove
Czech Republic	Flexove
Denmark	Glucomed

France	Flexea
Hungary	Flexove
Iceland	Glucomed
Ireland	Flexove
Italy	Flexove
Netherlands	Glucomed
Norway	Flexove
Poland	Flexove
Portugal	Glucomed
Slovakia	Glucomed
Sweden	Glucomed
United Kingdom	Flexove

This leaflet was last approved on: DD-MM-2016

Detailed information on this medicinal product is available on the website of www.hpra.ie