OTC
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Package Leaflet: Information for the User

<Invented Name> 750 mg Film-Coated Tablets

Glucosamine Sulfate

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.

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 1 month.

What is in this leaflet

1. What <Invented Name> is and what it is used for
<Invented Name> belongs to a group of medicines called other anti-inflammatory and anti-rheumatic agents, non steroids.
<Invented Name> is used 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 sleep or long rest) and pain at motion (e.g. when climbing the stairs or walking along uneven surfaces).

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2. What you need to know before you take <Invented Name>

DO NOT TAKE <Invented Name>
- If you are allergic to:
  - Glucosamine or to any of the other ingredients of <Invented Name> (see Section 6 "Contents of the pack and other Information")
  - Shellfish, since <Invented Name> is manufactured from shellfish.

Warnings and precautions

TAKE SPECIAL CARE with <Invented Name> if you
- Suffer from impaired glucose tolerance. More frequent controls of your blood glucose levels may be necessary when starting treatment with <Invented Name>
- Have kidney or liver dysfunction, since no studies have been performed in such patients dose recommendations cannot be given.
- Have a known risk factor for heart (cardiovascular) disease, since high cholesterol (hypercholesterolemia) has been observed in a few cases in patients treated with <Invented Name> .
- Suffer with asthma. When starting on <Invented Name> , you should be aware of potential worsening of symptoms.
- If you have joint swelling, warmth and redness, joint painfulness, persistent joint stiffness, pain at rest, pain in more than one joint, increased body temperature and decrease in body weight because they can be symptoms of more serious diseases such as rheumatoid arthritis, systemic lupus, gout, tumours.

Consult a doctor before using <Invented Name> if any of the above mentioned applies to you.

Children and adolescents:
<Invented Name> tablets should not be used in persons under the age of 18 years.

Other medicines and <Invented Name>
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Caution should be exercised if <Invented Name> has to be combined with other medicines, especially with:
- Warfarin (a medicine used to thin the blood) or similar type of products (anticoagulents used to prevent blood-clotting). The effect of the anticoagulant may be intensified in association with glucosamine. Patients treated with such combinations should therefore be monitored extra carefully when initiating or ending glucosamine therapy.
- Medicines for diabetes, your doctor may wish to monitor your blood sugar levels closely while you are taking <Invented Name>
- Tetracycline (an antibiotic effective against a wide range of bacterial infections).

Please contact your doctor or pharmacist for medical advice before using <Invented Name> if you use any of the above mentioned medicines.

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Taking <Invented Name> with food and drink
You can take <Invented Name> with or without food.

Pregnancy, breast-feeding and fertility
<Invented Name> should not be used during pregnancy. The use of <Invented Name> during breast-feeding is not recommended. Ask your doctor or pharmacist for advice before taking any 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 <Invented Name> , you should not drive or operate machinery.

Important information about some of the ingredients of <Invented Name>
This medicinal product contains 76 mg sodium per tablet. This should be taken into consideration by patients on a controlled sodium diet. <Invented Name> contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. <Invented name> contains soya lecithin. Do not use this product if you are allergic to soya or peanuts.

3. How to take <Invented Name>

Always take <Invented Name> exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

One <Invented Name> tablet should be taken twice daily or two <Invented Name> tablets to be taken once daily. The tablets should be swallowed whole with water.

<Invented Name> is not indicated for the treatment of acute painful symptoms (rapid onset of brief severe pain). 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 <Invented Name> should be re-evaluated and medical advice sought.

Use in children and adolescents
<Invented Name> is not recommended for use in children and adolescents below the age of 18, due to lack of data on safety and efficacy.

Elderly
No dosage adjustment is required when treating otherwise healthy elderly patients, however your doctor will decide your dose.

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

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If you take more <Invented Name> than you should
If you have taken large quantities you must consult your doctor or a hospital.
In case of an overdose you may experience symptoms such as:
headache
dizziness
disorientation
joint pain
feeling sick (nausea) or being sick (vomiting)
diarrhoea or constipation.

If you forget to take <Invented Name>
Do not take a double dose to make up for a forgotten dose.

If you stop using <Invented Name>
Your symptoms may reoccur. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, <Invented Name> can cause side effects, although not everyone gets them.
You should stop taking <Invented Name> and see your doctor immediately if you experience symptoms such as: swollen face, tongue and/or pharynx and/or difficulty to swallow or hives together with difficulties to breathe (angioedema).

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

Uncommon side-effects (in less than 1 in 100 patients but more than 1 in 1000 patients treated)
- Rash
- Itching
- Flushing

Unknown frequency
- Allergic reaction
- Visual disturbance
- Hair loss (alopecia)

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- Dizziness
- Swelling of the feet or ankles
- Vomiting
- Diabetes mellitus inadequate control
- Asthma or aggravation of pre-existing asthma
- Increased liver enzymes (hepatic enzyme elevation)
- Yellow discoloration of the skin (jaundice)

Elevated cholesterol levels have been also reported. It is not possible to determine whether these events were directly related to <Invented Name>

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 <Invented Name>

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.
Do not use <Invented Name> after the expiry date which is stated on the label and carton after EXP:. The expiry date refers to the last day of that month.
After first opening of the tablet container the product should be used within 6 months.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer needed. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented Name> contains
The active substance is glucosamine sulfate. Each tablet contains 942 mg of glucosamine sulfate sodium chloride (equivalent to 750 mg of glucosamine sulfate) or 589 mg glucosamine.

The other ingredients are
Tablet: microcrystalline cellulose 101, microcrystalline cellulose 102, lactose monohydrate, pregelatinised maize starch, crospovidone, stearic acid,
Coating: poly(vinyl) alcohol, titanium dioxide (E171), talc (E553b), Lecithin soya (E322), macrogol 3350.

What <Invented Name> looks like and contents of the pack
<Invented Name> 750 mg tablets are off-white, oblong, film-coated tablets, 8x19mm.

The tablets are available in two types of packaging:

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Cartons containing PVdC coated PVC/Al blisters.
Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180, 336, 360 film-coated tablets.
or
Cartons containing HDPE containers fitted with a tamper-evident HDPE screw cap.
Pack Size: 8, 10, 12, 14, 20, 28, 30, 56, 60, 112, 120, 168, 180, 336, 360 film-coated tablets.
Not all pack sizes may be marketed.

Marketing authorisation holder
<To be completed nationally>

Manufacturers

Chanelle Medical, Loughrea, Co.Galway, Ireland.

Walmark a.s, Oldřichovice 44, 739 61 Třinec, Czech Republic.

Millmount Healthcare Ltd., Block 7, City North Business Campus, Stamullen, County Meath, Ireland

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

<To be completed nationally>

This leaflet was last revised in: