Arthrimel

Glucosamine Sulfate

750mg Film-coated Tablets

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.
- You must talk to a doctor if you do not feel better or if you feel worse after 1 month.

In this leaflet:

1. What Arthrimel® is and what it is used for
Arthrimel® belongs to a group of medicines called other anti-inflammatory and anti-rheumatic agents, non-steroids. Arthrimel® is used for the relief of symptoms of mild to moderate osteoarthritis of the knee that has previously been diagnosed by your doctor.

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).

2. Before you take Arthrimel®
DO NOT TAKE Arthrimel®

- If you are allergic (hypersensitive) to:
- Glucosamine or to any of the other ingredients of Arthrimel® (see Section 6 “Further Information”)
- Shellfish, since Arthrimel® is manufactured from shellfish.

TAKE SPECIAL CARE with Arthrimel® if you
- Suffer from impaired glucose tolerance. More frequent controls of your blood glucose levels may be necessary when starting treatment with Arthrimel®
- Have kidney or liver dysfunction, since no studies have been performed in such patient’s 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 Arthrimel®.
- Suffer with asthma. When starting on Arthrimel®, 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 Arthrimel ®.if any of the above mentioned applies to you.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Caution should be exercised if Arthrimel® 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 Arthrimel®
- Tetracycline (an antibiotic effective against a wide range of bacterial infections).

Please contact your doctor or pharmacist for medical advice before using Arthrimel ® if you use any of the above mentioned
medicines.

Taking Arthrimel® with food and drink

You can take Arthrimel® with or without food**.**

Pregnancy and breast-feeding
Arthrimel® should not be used during pregnancy. The use of Arthrimel® 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 Arthrimel®, you should not drive or operate machinery.

Important information about some of the ingredients of Arthrimel®
This medicinal product contains 76 mg sodium per tablet. This should be taken into consideration by patients on a controlled sodium diet. Arthrimel® 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. Arthrimel ® contains soya lecithin. Do not use this product if you are allergic to soya or peanuts.

3. How to take Arthrimel ®
Always take Arthrimel® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

One Arthrimel® tablet should be taken twice daily or Two Arthrimel tablets to be taken once daily. The tablets should be swallowed whole with water.

Arthrimel® 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 Arthrimel® should be re-evaluated by your healthcare practitioner. You should stop taking Arthrimel® and see your doctor if you experience any deterioration in symptoms after starting Arthrimel®.

Children and adolescents
Arthrimel® 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.

If you take more Arthrimel® 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 Arthrimel®
Do not take a double dose to make up for a forgotten dose.

If you stop using Arthrimel®
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, Arthrimel® can cause side effects, although not everyone gets them.
You should stop taking Arthrimel ® 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)

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

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

Elevated cholesterol levels have been also reported. It is not possible to determine whether these events were directly related to Arthrimel ®

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
E-mail: imbpharmacovigilance@imb.ie

5. How to store Arthrimel®
Keep out of the reach and sight of children.
Do not store above 25°C. Store in the original package in order to protect from moisture.
Do not use Arthrimel® after the expiry date stated on the label and carton after EXP:. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information
What Arthrimel® contains
The active substance is glucosamine sulfate. Each tablet contains 942 mg of glucosamine sulfate sodium chloride (equivalent to 750 mg of glucosamine sulfate).

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

What Arthrimel® looks like and contents of the pack
Arthrimel®750 mg tablets are off-white, oblong, film-coated tablets.
The tablets are available in two types of packaging:

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.

This leaflet was last approved In November 2014.
Arthrimel ® is a registered Trademark.

Marketing authorisation holder
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Bracetown Business Park,
Clonee, Co. Meath, Ireland.