

Arthriex 1500mg Film Coated Tablets Glucosamine Sulfate

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 2-3 months.

What is in this leaflet

1. What Arthriex 1500 mg Film Coated Tablets are and what they are used for
2. What you need to know before you take Arthriex 1500 mg Film Coated Tablets
3. How to take Arthriex 1500 mg Film Coated Tablets
4. Possible side effects
5. How to store Arthriex 1500 mg Film Coated Tablets
6. Contents of the pack and other information

1. What Arthriex 1500 mg Film Coated Tablets are and what they are used for

This medicine belongs to a group of medicines called other anti-inflammatory and anti-rheumatic agents, non steroids.

This medicine should only be used for the relief of symptoms (signs of illness) of mild to moderate osteoarthritis of the knee that has previously been diagnosed by your doctor. Glucosamine is not indicated for the treatment of acute painful symptoms. Please make sure that you have been diagnosed with osteoarthritis of the knee before taking this product.

Mild to moderate osteoarthritis of the knee is a type of joint disease with signs of illness such as stiffness (after sleep or long rest) and pain when you move (e.g. when climbing the stairs, kneeling, bending, walking or running).

This medicine is to be used only for the treatment of mild to moderate osteoarthritis of the knee. This medicine is not to be used for the treatment of any other areas of your body affected by osteoarthritis or to treat other types of arthritis e.g. rheumatoid arthritis.

You must talk to a doctor if you do not feel better or if you feel worse after 2-3 months.

2. What you need to know before you take Arthriex 1500 mg Film Coated Tablets

Do not take Arthriex 1500 mg Film Coated Tablets

- If you are allergic to Glucosamine or to any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to Shellfish, since Glucosamine sulfate tablets are manufactured from shellfish.
- If you are allergic to peanut or soya.
- If you are taking Warfarin (a medicine used to thin the blood) or similar type of products (anticoagulants used to prevent blood-clotting) as Glucosamine may increase the effect of Warfarin making blood clotting even slower. This could cause bruising and bleeding that can be serious.
- If you are taking oral tetracycline (an antibiotic effective against a wide range of bacterial infections) do not take Glucosamine at the same time.
- If you are pregnant or breast-feeding.
- If you have kidney or liver problems (discuss with your doctor if you are not sure).

Warnings and precautions

Talk to your doctor or pharmacist before taking this product if you:

- Suffer from impaired glucose tolerance or diabetes (type I or II). More frequent monitoring of your blood glucose levels may be necessary when starting treatment with Glucosamine tablets and regularly during treatment and when discontinuing from Glucosamine.

- Have a known risk factor for heart (cardiovascular) disease, since high cholesterol (hypercholesterolemia) has been observed in a few cases in patients treated with Glucosamine tablets. Monitoring of cholesterol levels is therefore recommended during treatment with Glucosamine.
- Suffer with asthma. When starting on Glucosamine tablets, you should be aware of potential worsening of symptoms (your signs of illness).
- 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 (signs of illness) of more serious diseases such as rheumatoid arthritis, systemic lupus, gout, tumours.
- Experience a benefit from taking this medicine and intend to continue using it for over 3 months, please discuss this with your doctor.

Talk to your doctor before using Arthriex 1500 mg Film Coated Tablets if any of the above mentioned applies to you.

Other medicines and Arthriex 1500 mg Film Coated Tablets

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

Caution should be exercised if Arthriex 1500 mg Film Coated Tablets have to be combined with other medicines, especially with:

- Medicines for diabetes, as your doctor or pharmacist or nurse may wish to monitor your blood sugar levels more closely while you are taking this medicine.

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

Arthriex 1500 mg Film Coated Tablets with food and drink

You can take this medicine with or without food.

Pregnancy and breast-feeding

This medicine should not be used during pregnancy because there is not enough information available on the use of Glucosamine in pregnant women. This medicine should not be used during breast-feeding because there is no information available on the risk to your child.

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 this medicine, you should not drive or operate machinery.

Arthriex 1500 mg Film Coated Tablets contain

This medicinal product contains 152 mg sodium per tablet. This should be taken into consideration by patients on a controlled sodium diet. This medicine 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 because your blood sugar levels will need to be checked regularly when you are taking it. This medicine contains soya lecithin. Do not use this product if you are allergic to soya or peanuts.

3. How to take Arthriex 1500 mg Film Coated Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. One tablet should be taken once daily. The tablets should be swallowed whole with water. Glucosamine is not indicated for the treatment of acute painful symptoms.



Arthriex 1500mg Film Coated Tablets

Glucosamine Sulfate

You may notice that the relief of your symptoms (signs of illness) might not happen for several weeks of treatment and in some cases may take even longer. If you do not feel any better after 2-3 months, you should speak to your doctor, pharmacist or nurse to find out if you should continue taking this medicine.

Use in children and adolescents

This medicine is not recommended for use in children and adolescents below the age of 18, because safety and efficacy has not been established.

Use in elderly

No dosage adjustment is required when treating otherwise healthy elderly patients. Please speak to your doctor if you are not sure of the dose you should be taking.

If you take more Arthriex 1500 mg Film Coated Tablets 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 (signs of illness) such as:

- headache
- dizziness
- disorientation
- joint pain
- feeling sick (nausea) or being sick (vomiting)
- diarrhoea or constipation.

If you forget to take Arthriex 1500 mg Film Coated Tablets

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

If you stop using Arthriex 1500 mg Film Coated Tablets

Your symptoms (signs of illness) 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, this medicine can cause side effects, although not everyone gets them. You should stop taking Arthriex 1500 mg Film Coated Tablets and see your doctor immediately or go to the casualty department at your nearest hospital if you experience signs of illness 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)
- 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 Glucosamine tablets.

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arthriex 1500 mg Film Coated Tablets 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 this medicine after the expiry date 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 you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Arthriex 1500 mg Film Coated Tablets contain

- The active substance is Glucosamine sulfate. Each tablet contains 1884 mg of Glucosamine sulfate sodium chloride (equivalent to 1500 mg of glucosamine sulfate) or 1178 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 Arthriex 1500 mg Film Coated Tablets look like and contents of the pack

Arthriex 1500 mg Film Coated 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: 7, 10, 14, 20, 21, 28, 30, 56, 60, 84, 90 film-coated tablets.

or

Cartons containing HDPE containers fitted with a tamper-evident HDPE screw cap.

Pack Size: 7, 10, 14, 20, 21, 28, 30, 56, 60, 84, 90 film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder

TSI Health Sciences (Europe) Ltd., Warth Business Centre, Warth Road, Bury, BL9, 9TB, UK.

Manufacturers :

Walmark a.s, Oldrichovice 44, 739 61 Trinec, Czech Republic.