

PACKAGE LEAFLET: INFORMATION FOR THE USER
Osteole 1500mg powder for oral solution
Glucosamine Sulfate (as Glucosamine Sulfate Sodium Chloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Osteole is and what it is used for
2. Before you take Osteole
3. How to take Osteole
4. Possible side effects
5. How to store Osteole
6. Further information

1. WHAT OSTEOLE IS AND WHAT IT IS USED FOR
Osteole 1500mg powder for oral solution is used to treat the symptoms of osteoarthritis, i.e. pain and stiffness.

2. BEFORE YOU TAKE OSTEOLE
Do NOT take Osteole if you:

- are allergic (hypersensitive) to glucosamine sulfate, sodium chloride or any of the other ingredients of Osteole (*see Section 6 and end of Section 2*)
- have phenylketonuria (an enzyme deficiency condition). This product contains aspartame.

Take special care with Osteole if you:

- have kidney or liver problems; administration of this medicine should be under medical supervision.
- have diabetes or are fructose or glucose intolerant; close monitoring of blood sugar levels may be necessary at the beginning of treatment.
- are allergic to shellfish, because this is where glucosamine is obtained from.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, particularly as the effects of the following medicines may be increased:

- warfarin (used to prevent blood clotting)
- tetracyclines (antibiotics)

Taking Osteole with food and drink
This medicine should preferably be taken at a meal time.

Pregnancy and breast-feeding
Do NOT take Osteole during the first three months of pregnancy. Osteole should only be taken by pregnant or breast-feeding women if advised to by a doctor. If you are trying for a baby, are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this or any other medicine.

Driving and using machines
Osteole may cause drowsiness or sleepiness. You should not drive or operate machinery until you know how the drug affects you.

Important information about some of the ingredients of Osteole

- **Sodium** - this medicine contains 151mg of sodium per dose; to be taken into consideration by patients on a sodium controlled diet.
- **Aspartame** - this is a source of phenylalanine which may be harmful for people with phenylketonuria.
- **Sorbitol** - if you know you have an intolerance to some sugars, tell your doctor before taking this medicine.

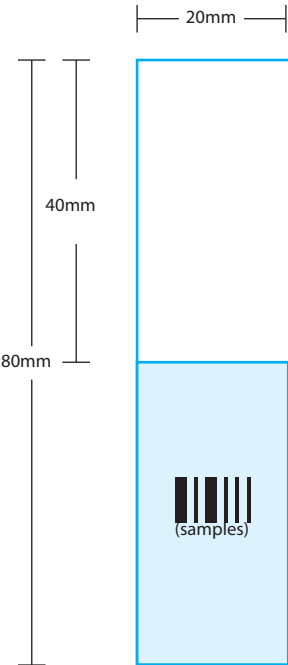
3. HOW TO TAKE OSTEOLE
Always take Osteole exactly as your doctor has told you; you should check with him/her if you are not sure.

Adults and the elderly - dissolve the contents of a single sachet in a glass of water and drink once a day, preferably at a meal time.
Children - not recommended.

24LF01179PD

barcode area

Text area



(samples)

If you take more Osteole than you should

If you, or someone else, have taken more medicine than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you if you can.

If you forget to take Osteole

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten one.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Osteole can cause side effects, although not everybody gets them.

STOP taking this medicine and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Common (occurring in less than 1 in every 10 patients)

- nausea, stomach pain, indigestion, passing wind, diarrhoea, constipation
- headache, drowsiness, sleepiness.

Uncommon (occurring in less than 1 in every 100 patients)

- skin rashes, including itching and redness.

Other (with unknown frequency)

- visual disturbances
- hair loss.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 OSTEOLE

Keep out of the reach and sight of children. Do not take Osteole after the expiry date (refers to the last day of that month) which is stated ‘EXP’ on the carton and sachet. There are no special storage conditions for this product. 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 protect the environment.

6. FURTHER INFORMATION

What Osteole contains

- The **active ingredient** is: Glucosamine Sulfate (as Glucosamine Sulfate Sodium Chloride). Each sachet contains glucosamine sulfate sodium chloride 1884mg equivalent to glucosamine sulfate 1500mg and sodium chloride 384mg.
- **Other ingredients:** aspartame (E951), macrogol 4000, anhydrous citric acid, sorbitol (E420) - *see also end of Section 2 for further information about some of the ingredients*.

What Osteole looks like and contents of the pack

Osteole is a white to slightly yellow, crystalline, odourless powder (1500mg) for oral solution. It is available in boxes containing 4, 20 or 30 sachets (not all pack sizes may be marketed).

Marketing Authorisation Holder

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary.

PA Number: 281/135/1

Manufacturers

Genepharm S.A., 18th klm Leof. Marathonos, 153 51 Pallini Attikis, Greece.
Alcala Farma S.L., Avenida de Madrid 82, 28802, Alcala de Henares, Madrid, Spain.
Kleva S.A. Parnithos Ave. 189, Acharnai Attiki 136 75, Greece.

This leaflet was last revised in November 2014

24LF01179PD

barcode area

Text area