

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dolenio 1500mg Film-coated
tablets

Glucosamine
Sulphate

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. 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 Dolenio is and what it is used for
2. What you need to know before you take Dolenio
3. How to take Dolenio
4. Possible side effects
5. How to store Dolenio
6. Contents of the pack and other information

1. WHAT DOLENIO IS AND WHAT IT IS USED FOR

Dolenio belongs to the group of other antiinflammatory and antirheumatic agents, non-steroids.

Glucosamine is a substance naturally occurring in the human body and necessary for joint fluid and cartilage.

Dolenio tablet is a medical product used for the relief of symptoms in mild to moderate osteoarthritis of the knee in adults.

Osteoarthritis is a type of joint degeneration which symptoms are: stiffness (after sleep or long rest), pain at motion (e.g. when climbing the stairs or walking along uneven surfaces), which relieves at a rest.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOLENIO

Do not take Dolenio

- if you are allergic to glucosamine or any of the other ingredients of this medicine (listed in section 6)..
- if you are allergic to shellfish, as the active ingredient glucosamine is extracted from shellfish.

Dolenio must not be used in children and adolescents under 18 years of age

Warnings and precautions

Glucosamine is not indicated for the treatment of acute pain.

Talk to your doctor or pharmacist before taking Dolenio. Particularly, tell your doctor:

- if you suffer of diabetes mellitus or have impaired glucose tolerance, it is recommended to

measure your blood glucose levels before the start of treatment and with regular intervals during the treatment.

- if you have a risk of cardiovascular disease (e.g. hypertension, diabetes mellitus, hypercholesterolemia or if you smoke), it is recommended to measure your cholesterol levels before the start of treatment since hypercholesterolemia has been observed in a few cases in patients treated by glucosamine.
- if you suffer from asthma. The treatment by glucosamine can worsen your asthma symptoms.

Children and adolescents

Dolenio should not be used in children and adolescents under 18 years of age.

Other medicines and Dolenio

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

It is particularly important to tell your doctor or pharmacist if you are taking any of the following medicines:

- tetracyclines (antibacterials used against infection)
- warfarin or similar type of products (anticoagulants 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.

Pregnancy and breast-feeding

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.

Pregnancy

Dolenio should not be used during pregnancy.

Breast-feeding

The use of Dolenio during breast-feeding is not recommended.

Driving and using machines

If you experience dizziness or drowsiness after you start taking **Dolenio**, you should not drive or operate machinery.

Dolenio contains sodium

One tablet contains 6.52 mmol (151 mg) of sodium. Please take into consideration if you are on a controlled sodium diet.

3. HOW TO TAKE **DOLENIO**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The recommended dose is 1178 mg of Glucosamine (1500 mg Glucosamine sulphate) to be taken once daily with a glass of water.

This corresponds to:

Dolenio 1500 mg – 1
tablet

When other strengths are available, the corresponding dosage is: Dolenio 750 mg – 2 tablets to be taken together, once daily. Dolenio 500 mg – 3 tablets to be taken together, once daily;

Older people

No dosage adjustment is required.

For oral use. The tablets should be swallowed together with some water or other liquid with or without meal.

Relief of symptoms (especially pain relief) may not be experienced until after several weeks of treatment and in some cases even longer. If you do not experience relief of symptoms after 2-3 months, please tell your doctor or pharmacist, since continued treatment with **Dolenio** should be re-evaluated.

If you take more **Dolenio than you should**

If you have taken too many **Dolenio** tablets, stop taking glucosamine and consult your doctor or go to a hospital.

Signs and symptoms of overdose with glucosamine might include headache, dizziness, confusion, joint pain, nausea, vomiting, diarrhoea or constipation, .

If you forget to take **Dolenio**

You should not take a double dose to make up for a forgotten dose.

If you stop taking **Dolenio**

Your symptoms may reoccur if you stop taking **Dolenio**.

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

4. POSSIBLE SIDE EFFECTS

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

You should stop taking **Dolenio** and see your doctor immediately or go to a hospital if you experience symptoms such as: swollen face, tongue and/or throat and/or difficulty swallowing/difficulty breathing or hives together with difficulties to breathe (angioedema).

The following side effects have been reported:

Common side effects (may affect up to 1 in 10 people): Headache, tiredness, nausea, abdominal pain, indigestion, diarrhoea, constipation.

Uncommon side effects (may affect up to 1 in 100 people): Rash, itching and flushing.

Frequency not known (can not be estimated from available data)

Vomiting, hives or itchy rash, dizziness, swelling of the feet or ankles. Aggravation of pre-existing asthma, blood glucose control worsened in diabetic patients.

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

Dolenio may cause liver enzyme elevation and rarely jaundice.

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 Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard. By reporting side effect you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOLENIO

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 package after EXP. The expiry date (EXP) refers to the last day of that month.

This medicine does not require any special storage conditions .

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What **Dolenio** contains

- The active substance is glucosamine. One tablet contains 1884.60 mg of Glucosamine sulphate sodium chloride equivalent to 1500 mg Glucosamine sulphate or 1178 mg glucosamine
- The other ingredients are
 - Core tablet**
 - Povidone K30
 - Macrogol 4000
 - Magnesium Stearate
 - Coating material**
 - Hypromellose
 - Titanium Dioxide (E171)
 - Talc
 - Propylene glycol
 - Polysorbate 80

What **Dolenio** looks like and contents of the pack

Dolenio is a white to off white, oval shaped, bi-convex film-coated tablet with break line on one side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack-sizes: 20, 30, 60 or 90 film-coated tablets in a HDPE bottles with HDPE screw cap.

4, 10, 20, 30, 45, 60, 90 film coated tablets in Alu/PVC/PVDC blister packs.

Not all pack sizes may be marketed.

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