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.

What is in this leaflet:

1. WHAT DOLENIO IS AND WHAT IT IS USED FOR

Dolenio belongs to the group of other anti-inflammatory and ant rheumatic agents, non-steroids.

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

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

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. BEFORE YOU TAKE DOLENIO

Do not take Dolenio
- if you are allergic to glucosamine or any of the other ingredients of Dolenio.
- if you are allergic to shellfish, as the active ingredient, glucosamine, is extracted from shellfish.
- if you are pregnant of breast-feeding.

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 control your glycaemia 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 control your cholesterol 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.
- if you have reduced kidney or liver function, since no studies with glucosamine have been performed in this patient group.

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 (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.

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 Dolenio exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults
The usual dose is 1 tablet daily for adults.

Older people
No dosage adjustment is required.

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

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 to 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 pharynx and/or difficulty to swallow 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, urticaria, dizziness, swelling of the feet or ankles, angioedema. 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 hepatic enzyme elevation and rarely jaundice.

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:
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 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 tablets 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.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder
Blue Bio Pharmaceuticals Ltd.
5th Floor, Beaux Lane House, Mercer Street Lower
Dublin 2
Ireland

Manufacturer

Central-Pharma Limited
Caxton Road
Bedford
MK41 0XZ

<This medicinal product is authorised in the Member States of the EEA under the following names:>
Austria: Tavimin 1500 mg Filmtabletten
Belgium: Dolenio 1178mg Filmomhulde tablet
Bulgaria: Bonartos 1178 мг филмирани таблетки
Czech Republic: Bayflex 1178 mg
Cyprus: Dolenio
Germany: Dolex 1500 mg Filmtabletten
Denmark: Dolenio
Estonia: Dolenio

France: Dolenio 1178 mg, comprimé pelliculé

Greece: Dolenio
Hungary: Dolenio 1500 mg filmtabletta
Iceland: Dolenio
Ireland: Dolenio 1500mg Film-coated tablets
Lithuania: Dolenio 1178 mg plėvele dengtos tabletės
Luxembourg: Dolenio 1178 mg, comprimé pelliculé
Latvia: Dolenio 1178 mg apvalkotās tablets
Malta: Dolenio
The Netherlands: Dolenio 1178 mg filmomhulde tablet
Poland: Dolenio
Portugal: Dolenio
Romania: Slideflex 1178 mg, comprimate filmate
Sweden: Dolenio 1178 mg filmdragerade tabletter
Slovenia: Dolenio 1178 mg filmsko obložene tablete
Slovakia: Dolenio 1178 mg
United Kingdom: Dolenio 1500 mg Film-coated tablets

This leaflet was last revised in 06/2016.