6. FURTHER INFORMATION

What Doloritis contains

The active substance is glucosamine sulfate. One tablet contains 1884.60 mg of glucosamine sulfate sodium chloride equivalent to 1500 mg glucosamine sulfate 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 Doloritis looks like and contents of the pack

Doloritis 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.

2, 4, 10, 20, 30, 45, 60, 90, 180 film coated tablets in Alu/PVC/PVDC blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

AHA Medical Services Ltd

6 Cathedral Park, Belmont

Industrial Estate, Durham, DH1 1TF

United Kingdom.

Manufacturer

Jemo-Pharm A/S,

Hasselvej 1,

DK-4780 Stege,

Denmark

This leaflet was last approved in XXXXXX

Doloritis

1500 mg film-coated tablets

Glucosamine sulfate

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This medicine is available without prescription. However, you still need to take Doloritis carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 2 to 3 months.
- 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.

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1. WHAT DOLORITIS IS AND WHAT IT IS USED FOR

Doloritis 1500 mg film-coated tablets belong to the group of other anti-inflammatory and anti-rheumatic agents, non-steroids.

Glucosamine is a substance naturally occurring in the human body and is necessary for joint fluid and cartilage (the soft tissue that surrounds the ends of your bones).

Doloritis 1500mg film-coated tablets are a medical product used in management of chronic knee stiffness and pain after periods of immobility.

Doloritis 1500 mg film-coated tablets are also used in Osteoarthritis, as pre-diagnosed by a doctor.

If you have a doubt or if you have other symptoms other than those described above, please talk to your doctor who will rule out the presence of joint diseases for which other treatment should be considered.

2. BEFORE YOU TAKE DOLORITIS

Do not take Doloritis

- If you are allergic (hypersensitive) to glucosamine or any of the other ingredients of Doloritis.
- If you are allergic (hypersensitive) to shellfish, as the active ingredient, glucosamine, is extracted from shellfish.
- If you are pregnant.

Doloritis must not be used in children under 18 years of age.

Take special care with Doloritis

Consult your doctor before taking Doloritis.

- If you suffer from diabetes mellitus or have impaired glucose tolerance. It is recommended to make control your glycaemia before the start of treatment and with regular intervals during the treatment.

Artwork prepared by BlueBio Pharmaceuticals Ltd

Product Title	**Doloritis PIL - 2s, 4s, 10s, 20s, 30s, 45s, 60s, 90s, 180s**		
Market	Ireland	Dimension (height)	205 mm
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EAN Code	-	Dimension (length)	-
Pharma Code	-	Final dimension	91x238
Material Code	-	Scale	1:1

Printing color: Pantone 286C

Pantone 3005C

Typefaces: AvantGarde MD BT, Swiss 721 BlkCN BT, Swiss 721 CN BT

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- If you have a known risk factor for cardiovascular disease (e.g.high blood pressure (hypertension), diabetes mellitus, high cholesterol levels or if you smoke). It is recommended to measure your cholesterol levels before starting treatment since hypercholesterolemia (higher levels of cholesterol) has been seen in a small number of people treated with glucosamine.
- If you suffer from asthma, the use of glucosamine can worsen asthma symptoms.

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.

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

- Tetracyclines (antibacterial used against infection).
- Warfarin or similar types of products (anticoagulants used to prevent blood-clotting). The effect of the anticoagulant may be increased in association with glucosamine.
- Do not take additional food supplements which may contain glucosamine whilst using Doloritis tablets.

Pregnancy and breast-feeding

Pregnancy

Ask your doctor or pharmacist for information, before you take any kind of medicine.

Doloritis should not be used during pregnancy.

Breast-feeding

Ask your doctor or pharmacist for information, before you take any kind of medicine.

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

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 after you start taking Doloritis you should not drive or operate machinery.

Important information about some ingredients of Doloritis

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 DOLORITIS

Always take Doloritis exactly as described. You should check with your doctor or pharmacist if you are not sure.

Adults aged 18 years and older

The dose is 1 tablet daily for adults.

The tablet should be swallowed whole with some liquid, and can be taken with or without food.

Elderly

No dosage adjustment is required.

Children and adolescents

Doloritis tablets should not be given to or used by children and adolescents under 18 years of age.

Glucosamine is not indicated for the treatment of acute pain. Relief of knee 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 your symptoms after 2-3 months, please tell your doctor or pharmacist, since continued treatment with Doloritis should be re-evaluated.

For oral use.

If you take more Doloritis than you should

If you have taken too many tablets, consult your doctor or hospital. Signs and symptoms of overdose with glucosamine might include headache, dizziness, confusion, joint pain, feeling sick, vomiting, diarrhoea or constipation, Stop taking glucosamine at signs of overdose.

If you forget to take Doloritis

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

If you stop taking Doloritis

Your symptoms may reoccur if you stop taking Doloritis Tablets.

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

4. POSSIBLE SIDE EFFECTS

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

You should stop taking Doloritis and see your doctor immediately if you experience any of the following: swelling of your face, tongue and/or throat, difficulty in breathing or swallowing which may be an allergic reaction (angioedema).

The following side effects have been reported:

Common side effects (affects 1 to 10 users in 100): Headache, tiredness, feeling sick, abdominal pain, indigestion, diarrhoea, constipation and flatulence.

Uncommon side effects (affects 1 to 10 users in 1,000): Rash, itching and flushing.

Frequency not known (cannot be estimated from available data)

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

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

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.

5. HOW TO STORE DOLORITIS

Keep out of the reach and sight of children.

Do not use Doloritis after the expiry date which is stated on the carton, bottle and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Once opened use within 6 months for HDPE bottles.

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.

Artwork prepared by BlueBio Pharmaceuticals Ltd

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AHA Medical Services Ltd

6 Cathedral Park, Belmont

Industrial Estate, Durham, DH1 1TF

United Kingdom.

Manufacturer

Central-Pharma Limited

Caxton Road

Bedford, MK41 0XZ

United Kingdom

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Doloritis

1500 mg film-coated tablets

Glucosamine sulfate

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Pregnancy

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Doloritis should not be used during pregnancy.

Breast-feeding

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

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 after you start taking Doloritis you should not drive or operate machinery.

Important information about some ingredients of Doloritis

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Elderly

No dosage adjustment is required.

Children and adolescents

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For oral use.

If you take more Doloritis than you should

If you have taken too many tablets, consult your doctor or hospital. Signs and symptoms of overdose with glucosamine might include headache, dizziness, confusion, joint pain, feeling sick, vomiting, diarrhoea or constipation, Stop taking glucosamine at signs of overdose.

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6 Cathedral Park, Belmont

Industrial Estate, Durham, DH1 1TF

United Kingdom.

Manufacturer

Wasdell Packaging Limited

Units 6 -8, Euroway Industrial Estate

Blagrove

Swindon

Wiltshire, SN5 8YW

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Doloritis

1500 mg film-coated tablets

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