

Package Leaflet: Information for the user
DONA 500mg capsules
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 pharmacist has 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 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 30 days.

What is in this leaflet:

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

1. What Dona is and what it is used for

Dona contains glucosamine sulfate which belongs to a group of medicines called non-steroidal anti-inflammatory and anti-rheumatic agents.

Dona is used for the relief of symptoms in mild to moderate osteoarthritis of the knee, as diagnosed by your doctor.

2. What you need to know before you take Dona

Do not take Dona:

- If you are allergic (hypersensitive) to glucosamine or any of the other ingredients of Dona.
- If you are allergic to shellfish, as glucosamine is obtained from shellfish.

Warnings and precautions

Consult your doctor before taking Dona:

- If you have diabetes; in this case closer monitoring of blood sugar levels and where relevant insulin requirements may be necessary at the beginning of the treatment and periodically during treatment with Dona.
- If you suffer from asthma; when starting on glucosamine, you should be aware of potential worsening of symptoms.
- If you have severe liver or kidney problems.
- If you are on a controlled sodium diet.

The presence of another joint disease, which would require alternative treatment, should be excluded.

If unusual signs or symptoms appear, or if any changes in the course of usual symptoms occur, the patient is recommended to consult the physician immediately.

Children and adolescents

Dona should not be used in children and adolescents below the age of 18 years.

Other medicines and Dona

Caution should be exercised if Dona has to be combined with other medicines, especially with:

- Some types of medicines used to prevent blood clotting (e.g. warfarin, dicoumarol, phenprocoumon, acenocoumarol and fluidione). The effect of these medicines may be stronger when used with glucosamine. Patients treated with such combinations should therefore be monitored extra carefully when initiating or ending glucosamine therapy.

The effect of coumarinic anticoagulants (a group of drugs used to prevent blood clotting) may increase during treatment with glucosamine. Inform your doctor if you are using these medicines. In case of concomitant treatment your doctor may consider a closer monitoring of the coagulation parameters when initiating or ending glucosamine therapy.

The administration of Dona can enhance the gastrointestinal absorption of tetracyclines (a group of broad-spectrum antibiotics).

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

Dona with food and drink

Dona should be taken preferably at meals.

Pregnancy and breast-feeding

Dona should not be used during pregnancy and breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine

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Driving and using machines

No studies of the effects on the ability to drive and use machines have been performed. If you experience headache, somnolence, tiredness, dizziness or visual disturbances while taking Dona, you should not drive or operate machinery.

Dona contains sodium

This medicine contains 50.3 mg sodium (main component of cooking/table salt) in each capsule. This is equivalent to 2.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Dona

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

Use in adults including older people

The dose is one capsule three times daily, preferably at meals. Glucosamine is not indicated for the treatment of acute painful symptoms. Relief of symptoms (especially pain relief) may not be experienced until after some weeks of treatment or sometimes even longer. If no relief of symptoms is experienced after 2-3 months, continued treatment with glucosamine should be re-evaluated by your doctor.

Patients should seek medical advice if their symptoms deteriorate after commencing treatment with glucosamine.

Use in children and adolescents

Dona should not be used in children and adolescents below the age of 18 years.

Use in patients with impaired renal and/or liver function

No dose recommendation can be given since no studies have been performed.

If you take more Dona than you should

If you take more Dona than you should, you must consult your doctor, pharmacist or a hospital.

If you forget to take Dona

Take the next dose as planned.

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

If you stop taking Dona

Your symptoms may re-occur.

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

4. Possible side-effects

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

Stop taking Dona and consult your doctor immediately if signs of allergic reactions occur (e.g. hypersensitivity reactions such as itching and skin rashes). Severe allergic reactions may occur in predisposed patients.

The following side-effects have been reported:

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

- headache
- somnolence (sleepiness or drowsiness)
- tiredness
- diarrhoea
- constipation
- nausea
- flatulence (presence of gasses in the digestive tract)
- abdominal pain
- indigestion (dyspepsia)

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

- redness of the skin (erythema)
- flushing
- pruritus (itching)
- skin inflammation (cutaneous rashes)

Other side effects (with unknown frequency)

- dizziness
- an increase in certain liver enzymes (hepatic enzyme elevation) and yellowing of the skin or whites of the eyes (jaundice)
- visual disturbances
- insomnia (difficulty in getting to sleep or staying asleep)

- hair loss
- irregular heartbeat (cardiac arrhythmia)
- poor diabetes control
- asthma
- vomiting
- excessive fluid in the tissues (oedema)
- An increase in certain liver enzymes (hepatic enzyme elevation) and yellowing of the skin or whites of the eyes (jaundice).

If any of these 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 HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dona

Keep Dona out of the sight and reach of children.

No special storage conditions are required.

Dona should be stored in its intact packaging.

Do not use Dona after the expiry date which is stated on the carton or on the bottle.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Dona contains

One capsule contains 500 mg of the active substance glucosamine sulfate

The other ingredients are: talc and magnesium stearate. The capsule shell contains: erythrosine (E127), red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172), gelatine. The black ink used for printing the logo ROTTA contains: shellac glaze, black iron oxide (E172), propylene glycol.

What Dona looks like and content of the pack

Dona is a hard red-red capsule contained in a polyethylene bottle with a snap on neck provided with a cap and a removable security closure system.

Pack sizes: 60 and 90 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland

Manufacturer

ROTTAPHARM Limited,
Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland

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