Package leaflet: Information for the user

DONA® 1500 mg powder for oral solution

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 your 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 to glucosamine or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to shellfish, as glucosamine is obtained from shellfish.

Warning 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 have high cholesterol levels in your blood
- If you have intolerance to some sugars.
- 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 changed 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.

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).

The pain relieving effect of glucosamine sulfate may be delayed for 1-2 weeks. If you suffer from pain during treatment with Dona, and especially in the beginning of treatment, you can additionally take a nonsteroidal analgesic (NSAID).

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.

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 aspartame, sorbitol and sodium
- Dona contains aspartame (E951) in each sachet. Aspartame is a source of phenylalanine. It may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- Dona contains sorbitol (E420) in each sachet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- One sachet contains 151 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 7.6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Dona

Always take this medicine 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 the content of one sachet (1500 mg glucosamine sulfate) daily, preferably at meals. Dissolve the powder from the sachet in a glass of water and drink.

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, stop taking Dona and 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, this medicine 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 (may affect up to 1 in 10 people)
- headache
- somnolence (sleepiness or drowsiness)
- tiredness
- diarrhoea
- constipation
- nausea
- flatulence (presence of gasses in the digestive tract)
- abdominal pain
- indigestion (dyspepsia)

Uncommon side effects (may affect up to 1 in 100 people)
- redness of the skin (erythema)
- flushing
- pruritus (itching)
- skin inflammation (cutaneous rashes)

Other side effects (frequency cannot be estimated from the available data)
- allergic reaction
- dizziness
- visual disturbances
- insomnia (difficulty in getting to sleep or staying asleep)
- irregular heartbeat (cardiac arrhythmia)
- poor diabetes control
- asthma
- vomiting
- excessive fluid in the tissues (oedema), angioedema, hives
- an increase in certain liver enzymes (hepatic enzyme elevation) and yellowing of the skin or whites of the eyes (jaundice).
- blood glucose increase
- blood pressure increase
- INR fluctuation

Cases of hypercholesterolaemia have been reported, but a causal link has not been demonstrated.

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 HPRA 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 this medicine out of the sight and reach of children.
Do not store above 25 °C.
Dona should be stored in its intact packaging.
Do not use this medicine after the expiry date which is stated on the carton and sachet. 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 you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dona contains
The active substance is glucosamine sulfate. Each sachet contains 1884 mg glucosamine sulfate sodium chloride (equivalent to glucosamine sulfate 1500 mg and sodium chloride 384 mg). Glucosamine sulfate sodium chloride is the new name for crystalline glucosamine sulfate. The ingredient itself has not changed.

The other ingredients are: aspartame (E951), macrogol 4000, citric acid (E330) and sorbitol (E420).

What Dona looks like and content of the pack
Dona is a white, crystalline, odourless powder contained in single-dose sachets.
Pack size: 30 sachets.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland

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

Parallel Product Authorisation Number:
PPA 465/401/1

Dona is a registered trademark of Rottapharm Ltd.

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