# PATIENT INFORMATION LEAFLET
# DONA® 1500mg
# Powder for Oral Solution
# Glucosamine Sulfate

***Read all this leaflet carefully before you start taking this medicine.***

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please 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 symptoms are the same as yours.*
- *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.*

*In this leaflet:*



## 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 treatment of the symptoms of osteoarthritis, i.e. pain and function limitation.

One sachet contains glucosamine sulphate sodium chloride 1884 mg, which is equivalent to glucosamine sulfate 1500 mg and sodium chloride 384 mg.

In addition to this the preparation contains the following excipients: aspartame (E951), Macrogol 4000, citric acid anhydrous, sorbitol (E420).

**Pharmaceutical form and presentation**

Powder for oral solution in single dose sachets. Package of 30 sachets

**Pharmaco-therapeutic group**

Dona® is a product for the treatment of the symptoms of osteoarthritis (ATC code M01AX05).

**Product procured from within the EU & repackaged by the parallel product authorisation holder.**

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

**Manufacturer**

Rottapharm Limited, Damastown Industrial Park, Mulhuddart, Dublin 15 or Rottapharm S.p.A., Via Valosa do Sopra, 9 – Monza, Italy or SIGMAR Italia S.r.l., Via Sombreno 11, Almé (BG) Italy.

## 2. 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 suffer from a genetic metabolic disorder (phenylketonuria).
- If you are allergic to shellfish, as glucosamine is obtained from shellfish.

**Take special care with Dona**

Consult your doctor before taking Dona:

- If you have diabetes; in this case closer monitoring of blood sugar levels at the beginning of the treatment with Dona may be necessary. 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 intolerance to some sugars.
- If you are on a controlled sodium diet.

Taking other medicines

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).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Taking 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 machinesNo studies of the effect 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.**Important information about some of the ingredients of Dona**

- Dona contains aspartame, which is a source of phenylalanine and may be harmful for people with phenylketonuria.
- Dona contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- One sachet contains 151 mg sodium. To be taken into consideration by patients on a controlled sodium diet.

**3. How to take Dona**Always take Dona exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Adults including the elderly**
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.
**Children and adolescents**
Dona should not be used in children and adolescents below the age of 18 years.
**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 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 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) ().
- pruritus (itching),
- skin inflammation (cutaneous rashes) (),

**Other side effects** (with unknown frequency):
- dizziness, visual disturbances
- hair loss
- 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.

**5. How to store Dona**

Do not store above 25°C.
Store in the original package in order to protect from moisture.
Dona should be stored in its intact packaging. Do not use Dona after the expiry date which is stated on the carton and sachetlabels after EXP. The expiry date refers to the last day of the month.
If your medicine shows any visible signs of deterioration, please ask your doctor or pharmacist for advice.
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.

**6. Further information**

**What Dona contains**

One sachet contains 1884 mg of the active substance 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 anhydrous (E330) and sorbitol (E420).

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

Dona is a white, crystalline, odourless powder contained in single-dose sachets.
Pack sizes: 30 sachets.

**Parallel Product Authorisation number: PPA 465/191/1**

**Repackaged and distributed by:**
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

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