

Package Leaflet: Information for the user

VIARTRIL[®] 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 contact a doctor if your symptoms worsen or do not improve after 30 days.

What is in this leaflet:

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

1. What Viartril is and what it is used for

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

Viartril 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 Viartril

Do not take Viartril:

- If you are allergic (hypersensitive) to glucosamine or any of the other ingredients of Viartril.
- If you suffer from a genetic metabolic disorder (phenylketonuria).
- If you are allergic to shellfish, as glucosamine is obtained from shellfish.

Warnings and precautions:

Consult your doctor before taking Viartril:

- 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 Viartril.
- 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.

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

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

Other medicines and Viartril

The administration of Viartril 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.

Caution should be exercised if Viartril 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

Viartril with food and drink

Viartril should be taken preferably at meals.

Pregnancy and breast-feeding

Viartril 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 Viartril, you not should drive or operate machinery.

Important information about some of the ingredients of Viartril

- Viartril contains 2.5mg 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.
- Viartril contains 2029mg 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.
- Viartril 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 Viartril

Always take Viartril 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

Viartril 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 Viartril than you should

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

If you forget to take Viartril

Take the next dose as planned. Do not take a double dose to make up for a forgotten one.

If you stop taking Viartril

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, Viartril can cause side effects, although not everybody gets them.

Stop taking Viartril 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
- visual disturbances
- insomnia (difficulty in getting to sleep or staying asleep)
- asthma
- hair loss
- irregular heartbeat (cardiac arrhythmia)
- poor diabetes control
- 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 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 Viartril

Keep Viartril out of the sight and reach of children.

Do not store Viartril above 25°C.

Viartril should be stored in its intact packaging.

Do not use Viartril after the use by date which is stated on the carton or on the sachet. The use by date refers to the last day of that month.

Do not throw away 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 Viartril contains

One sachet contains 1884 mg of the active substance glucosamine sulphate sodium chloride (equivalent to glucosamine sulfate 1500 mg and sodium chloride 384 mg)

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

What Viartril looks like and content of the pack

Viartril is a white, crystalline, odourless powder contained in single-dose sachets.

Pack sizes: 4, 20 and 30 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Distributed in Ireland by

This leaflet was last revised in August 2020