

Package leaflet: Information for the patient

Questran™ 4 g/sachet Powder for Oral Suspension, Colestyramine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Questran is and what it is used for

Questran contains the active substance colestyramine. Each sachet of Questran contains 4 g of colestyramine. Colestyramine belongs to a group of medicines called bile acid binding resins. Questran is used to lower your body's level of cholesterol (a type of fat) which can cause heart disease. This medicine works in the digestive system and absorbs the cholesterol-containing bile acids, which then pass out through the body in the faeces. Questran may also be used to help stop some types of diarrhoea or itching.

2. What you need to know before you take Questran

Do not take Questran if you:

- are **allergic** to colestyramine or any of the other ingredients of this medicine (listed in section 6).
- have an illness which results in your **bile duct being completely blocked** (e.g. gall stones). Check with your doctor if you are unsure.

Children

This medicine is **not suitable** for children **under 6 years** of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Questran if you are concerned about any of the following:

Long-term treatment with high doses of Questran may reduce the body's ability to absorb fat-soluble vitamins from the diet. These include vitamins A, D and K. Therefore your doctor may suggest you take a vitamin supplement.

If this medicine is being given to a child where there is a family history of high blood cholesterol levels, an additional supplement of folic acid may be advised.

Other medicines and Questran

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

If you are taking any other medicines it is **important** that they are taken at a different time to your dose of Questran.

Any other medicines should be taken **at least 1 hour before** you take your dose of Questran or **4 – 6 hours after** you have taken your dose of Questran.

This is because Questran may change the effects of other medicines by stopping them from working so well and Questran preparations can stay in the digestive system and can stop other medicines from being absorbed by the body.

Questran with food, drink and alcohol

It is recommended that your **alcohol** intake is kept within the recommended guidelines as advised by your doctor, as alcohol can increase your cholesterol level.

If you have been prescribed this medicine to reduce your cholesterol levels, it is recommended that you follow a low fat diet as advised by your doctor.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not take this medicine unless your doctor recommends it.

Driving and using machines

Questran has not been shown to impair your ability to drive or use machines.

Questran contains sucrose and propylene glycol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 3.79 g sucrose in each sachet, with a maximum daily dose of 34.11 g (i.e. 9 sachets). This should be taken into account in patients with diabetes mellitus.

The sucrose in Questran may be harmful to the teeth when used for a period of greater than 14 days.

This medicine contains 97.5 mg propylene glycol (as alginate) in each sachet.

If this medicine has been prescribed for a baby or a child that is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If the patient weighs less than 18 kg and suffers from a liver or kidney disease, do not give this medicine unless recommended by the doctor. The doctor may carry out extra checks while this medicine is being taken.

3. How to take Questran

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

To lower cholesterol levels

The usual dose is 3 – 6 sachets a day. This can be taken as a single dose or divided doses up to 4 times a day.

To relieve itching

The usual dose is one or two sachets each day.

To manage diarrhoea

The usual dose is 3-6 sachets a day. This can be taken as a single dose or divided doses up to 4 times a day.

Children (6 - 12 years)

The dose to be given to children will depend on the child's weight, which the doctor will work out for you.

Children under 6 years

This medicine is not recommended for children under the age of 6.

How to make up the sachets

1. The contents of one sachet should be sprinkled evenly on to 150 ml (4-6 fluid oz) of water or fruit juice.
2. Allow to stand for 1 or 2 minutes.
3. Once the powder has soaked into the liquid, stir or shake it to mix in thoroughly.

Do not take this medicine in its dry form as it may cause you to choke.

Questran can be mixed with water, fruit juice, skimmed milk, thin soups or fruit smoothies or sauces (e.g. apple sauce).

Keep taking your medicine until your doctor tells you to stop. Your doctor will want you to have regular check-ups whilst you are taking this medicine.

If you take more Questran than you should

Go to your nearest hospital Casualty Department or tell your doctor immediately. Take the empty container and any remaining sachets with you.

If you forget to take a dose

If you miss a dose do not worry. Take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and continue as before.

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

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

4. Possible side effects

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

The most frequent side effect seen is constipation. To minimise this effect you will usually start with a low dose and increase it slowly until you are taking the full number of sachets as prescribed by your doctor. This side effect usually reduces over time.

Other side effects include bloatedness, wind (flatulence), feeling sick (nausea) or vomiting, diarrhoea, heartburn, anorexia, indigestion (dyspepsia), problems with your body's ability to absorb food correctly leading to grey, bulky or smelly stools (steatorrhea). An increased tendency to bleed, which may also be seen with vitamin D, vitamin K or vitamin A deficiency. Vitamin A deficiency may rarely result in night blindness. An increased level of chloride in the blood (hyperchloremic acidosis) especially in children, thin or brittle bones (osteoporosis). Rash, itching, irritation of skin, tongue or around the anus, problems with swallowing or taste, rectal pain, belching, problems with liver function, shortness of breath, muscle and joint pains, headache, dizziness, tiredness, drowsiness, tingling or numbness, weight loss or gain and tooth decay. Rare reports of obstruction of the intestine have been seen.

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 HPRRA 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 Questran

Keep this medicine out of the sight and reach of children.

Do not store Questran above 30°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton and sachet after EXP. 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 Questran contains

The active substance in this medicine is colestyramine. Questran sachets each contain 4 g colestyramine.

The other ingredients in Questran are acacia, citric acid anhydrous, orange juice flavour, polysorbate 80, propylene glycol alginate, sucrose.

What Questran looks like and contents of the pack

Questran comes in the form of a powder and is supplied in packs of 50 sachets. Each sachet contains 9 g of powder.

This medicine is orange-flavoured.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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