QUESTRAN® LITE

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using QUESTRAN LITE?

QUESTRAN LITE contains the active ingredient colestyramine. QUESTRAN LITE is used to reduce high levels of cholesterol in the blood, provide relief of pruritis (itching) and provide relief of diarrhoea caused by surgery or disease of the small bowel. For more information, see Section 1. Why am I using QUESTRAN LITE? in the full CMI.

2. What should I know before I use QUESTRAN LITE?

Do not use if you have ever had an allergic reaction to QUESTRAN LITE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2.

What should I know before I use QUESTRAN LITE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with QUESTRAN LITE and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use QUESTRAN LITE?

- Your doctor will decide what dose you should receive.
- The usual dose for adults is 12 to 16 g of QUESTRAN LITE per day.
- QUESTRAN LITE must not be taken in its dry form; it must always be mixed with water, juice or other fluids before taking.

More instructions can be found in Section <u>4. How do I use QUESTRAN LITE?</u> in the full CMI.

5. What should I know while using QUESTRAN LITE?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using QUESTRAN LITE.
- If you plan to have surgery that needs a

	general anaesthetic, tell your doctor or dentist that you are taking QUESTRAN LITE. If you become pregnant while taking this medicine, tell your doctor immediately. Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	 Do not give your medicine to anyone else, even if they have the same condition as you. Do not stop taking your medicine or lower the dosage, without checking with your doctor. Do not take QUESTRAN LITE in its dry form. Always mix it with water or other fluids before you take it.
Driving or using machines	Be careful driving or operating machinery until you know how

	QUESTRAN LITE affects you.
Drinking alcohol	 Avoid drinking large quantities of alcohol.
Looking after your medicine	 Keep the sachets in a cool, dry place (below 30°C). Do not store QUESTRAN LITE in the bathroom, near a sink, on a window sill or in the car. Keep your tablets where children cannot reach it.

For more information, see Section <u>5. What should I know while using QUESTRAN LITE?</u> in the full CMI.

6. Are there any side effects?

Tell your doctor as soon as possible if you notice any of the following: constipation, haemorrhoids, abdominal pain, flatulence (wind/gas), nausea, vomiting, heartburn, diarrhoea, anorexia (loss of appetite), indigestion, steatorrhoea, rash and irritation of the tongue, skin or anal area, changes in bowel motions, chest pain, headache, anxiety, dizziness or drowsiness. For more information, including what to do if you have any side effects, see Section <u>6</u>. Are there any side effects? in the full CMI.

QUESTRAN® LITE

Active ingredient(s): colestyramine

Consumer Medicine Information (CMI)

This leaflet provides important information about using QUESTRAN LITE. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using QUESTRAN LITE.

Where to find information in this leaflet:

- 1. Why am I using QUESTRAN LITE?
- 2. What should I know before I use QUESTRAN LITE?
- 3. What if I am taking other medicines?
- 4. How do I use QUESTRAN LITE?
- 5. What should I know while using QUESTRAN LITE?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using QUESTRAN LITE?

QUESTRAN LITE contains the active ingredient colestyramine. QUESTRAN LITE belongs to a group of medicines called resins. It reduces the level of cholesterol in the blood by combining with bile in the small intestine to form an insoluble complex, which is then excreted in faeces.

The reduction of blood cholesterol levels helps to prevent blockages in the blood vessels to the heart which reduces the likelihood of angina (chest pain with heart disease) and heart attacks.

QUESTRAN LITE is used:

- to reduce high levels of cholesterol in the blood and assist in the prevention of coronary heart disease. It also used as an accompanying therapy to your diet in order to reduce cholesterol
- for the relief of pruritis (itching) associated with the flow of bile being partially blocked
- for the relief of diarrhoea caused by surgery or disease of the small bowel.

QUESTRAN LITE may be used alone or in combination with other medicines.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is not addictive.

This medicine is only available with a doctor's prescription.

The safety and effectiveness of using QUESTRAN LITE in infants and children has not been established.

2. What should I know before I use QUESTRAN LITE?

Warnings

Do not use QUESTRAN LITE if:

- you are allergic to any medicine containing colestyramine or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin

Always check the ingredients to make sure you can use this medicine.

- you have been diagnosed with complete biliary obstruction, where no bile is secreted into the intestine. A bile duct obstruction, also known as biliary obstruction, is where one of the ducts that carries bile from the liver to the intestine via the gallbladder becomes blocked.
- the expiry date (EXP) printed on the pack has passed or the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any medical conditions:
 - hypothyroidism
 - diabetes
 - nephrotic syndrome which is a kidney disorder that causes your body to excrete too much protein in your urine
 - liver problems
 - jaundice yellowing of the skin and eyes
 - phenylketonuria (PKU)
 - blood problems blood clotting associated with vitamin K deficiency
 - hyperchloraemic acidosis too much chloride in the blood
 - constipation

If you have not told your doctor about any of the above, tell them before you start taking QUESTRAN LITE.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and QUESTRAN LITE may interfere with each other. These include:

- thyroid and thyroxine preparations
- warfarin, a medicine used to prevent blood clots
- chlorothiazide, a diuretic which is used to help you excrete more urine
- tetracyclines, antibiotics which fight bacterial infections
- phenobarbital (phenobarbitone), a medicine used to treat epilepsy
- digitalis
- aldosterone antagonists, a diuretic which is used to help you excrete more urine
- inorganic iron
- estrogenic drugs

Do not stop taking QUESTRAN LITE if you have been taking a medicine with toxic side effect such as digitalis while you are using QUESTRAN LITE as this could be hazardous to your health.

These medicines may be affected by QUESTRAN LITE, or affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid, while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect QUESTRAN LITE.

4. How do I use QUESTRAN LITE?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Adults

 Maintenance or on-going therapy: 12 to 16 g of colestyramine resin equivalent to 14.1 to 18.8g of QUESTRAN LITE per day.

Children and Infants

 No dosage regimen has been established for children. Your doctor will start therapy in a child with small doses and adjust the dose, depending on the child's response to initial therapy.

How to take it

QUESTRAN LITE must not be taken in its dry form; it must always be mixed with water, juice or other fluids before taking.

- add the contents of the 4g sachet to 100 to 150 mL of water or fruit juice
- mix immediately by stirring vigorously
- continue to stir until the mixture is even (the powder will not dissolve)
- drink the entire mixture immediately, rinse the container and drink the rinse to ensure that you have taken the full dose

Make sure you use the full amount of water and ensure that it is well mixed before you drink it.

You can mix QUESTRAN LITE with thin soups or pulpy fruits with a high water content e.g. pureed apple or crushed pineapple. If care is taken you can mix it with carbonated drinks.

When to take QUESTRAN LITE

Take your medicine at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take your medicine.

If you are taking other medicines, you must take them one hour before taking QUESTRAN LITE or four to six hours after taking QUESTRAN LITE.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to use QUESTRAN LITE

If it is almost time for your next dose, skip the dose that you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If you are not sure of what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much QUESTRAN LITE

If you think that you have used too much QUESTRAN LITE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using QUESTRAN LITE?

Things you should do

 If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking QUESTRAN LITE.

- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking QUESTRAN LITE.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- Do not take QUESTRAN LITE to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage, without checking with your doctor.
- Do not take QUESTRAN LITE in its dry form.
 Always mix it with water or other fluids before you take it.

Driving or using machines

Be careful driving or operating machinery until you know how QUESTRAN LITE affects you.

As with other medicines QUESTRAN LITE may cause dizziness, light-headedness, drowsiness or tiredness in some people.

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid drinking large quantities of alcohol.

If you drink alcohol, your dizziness or lightheadedness may be worse.

Large quantities of alcohol may increase your chance of QUESTRAN LITE causing liver problems.

Things that would be helpful for lowering your cholesterol levels

A healthy diet and reduction in your weight is recommended before using QUESTRAN LITE for cholesterol reduction.

Looking after your medicine

Keep your sachets in a cool dry place where the temperature stays below 30°C.

Do not store QUESTRAN LITE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking QUESTRAN LITE.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
 constipation haemorrhoids The above list includes the more common side effects of your medicine. 	Tell your doctor or pharmacist if you notice any of the following and they worry you:

Serious side effects

Serious side effects	What to do
 abdominal pain flatulence (wind/gas) nausea vomiting heartburn diarrhoea anorexia (loss of appetite) indigestion steatorrhoea (the presence of excess fat in the faeces. Stools may be bulky and difficult to flush, have a pale and oily 	Tell your doctor as soon as possible if you notice any of the following serious side effects.

Serious side effects	What to do
appearance and can be especially foul-smelling)	
 rash and irritation of the tongue, skin or anal area 	
changes in bowel motions	
• chest pain	
• headache	
anxiety	
• dizziness	
drowsiness	
The above list includes serious side effects that may require medical attention.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What QUESTRAN LITE contains

Active ingredient (main ingredient)	850 mg per gram of colestyramine.
Other ingredients (inactive ingredients)	 aspartame citric acid colloidal anhydrous silica orange juice flavour 059107 AGEP0551 (ARTG PI No: 1291) propylene glycol alginate xanthan gum
Potential allergens	aspartame

Do not take this medicine if you are allergic to any of these ingredients.

What QUESTRAN LITE looks like

QUESTRAN LITE is a cream coloured, fine powder. It is available in sachets containing 4 g of cholestyramine. There are 50 sachets in the box. (AUST R 11971).

Who distributes QUESTRAN LITE

Viatris Pty Ltd

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Millers Point NSW 2000

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Phone: 1800 274 276

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