

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

QUESTRAN® LITE 4g/sachet Powder for Oral Suspension

Anhydrous Colestyramine

Contains sugar

Questran Lite contains 16,8 mg phenylalanine per sachet

Read all of this leaflet carefully before you start taking QUESTRAN LITE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- QUESTRAN LITE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What QUESTRAN LITE is and what it is used for:

The active ingredient in QUESTRAN LITE, colestyramine, belongs to a group of medicines called bile acid binding resins.

QUESTRAN LITE is used to lower your body's level of cholesterol (a type of fat) which can cause heart disease. If you have been prescribed QUESTRAN LITE to reduce your cholesterol levels, it is recommended that you follow a low fat diet as advised by your doctor.

QUESTRAN LITE works in the digestive system and absorbs the cholesterol-containing bile acids, which then pass out through the body in the faeces.

QUESTRAN LITE may also be used to help stop some types of diarrhoea or itching.

2. What you need to know before you take QUESTRAN LITE

Do not take QUESTRAN LITE:

- if you are hypersensitive (allergic) to colestyramine or any of the other ingredients (particularly aspartame) of QUESTRAN LITE.
- if you have an illness which results in your bile duct being completely blocked (e.g. gall stones). Please consult your doctor, pharmacist or other healthcare professional for advice.

The precise dosage of QUESTRAN LITE for children has not yet been established.

Warnings and precautions

Take special care with QUESTRAN LITE:

You should not take QUESTRAN LITE if you have exudative (the presence of pus in your stools) or bloody diarrhoea.

Before starting treatment with QUESTRAN LITE, diseases contributing to increased blood cholesterol such as hypothyroidism (low levels of thyroid hormones), diabetes mellitus (a condition that occurs when the body can't use glucose), nephrotic syndrome (kidney disorder) and obstructive liver disease should be investigated and specifically treated.

Additionally, you should attempt to control your cholesterol levels with an appropriate diet, weight reduction and the treatment of any underlying disorder which might be the cause of your high cholesterol, before you start treatment with QUESTRAN LITE. Your cholesterol levels should be determined frequently during the first few months of treatment and periodically thereafter. During the first month of treatment with QUESTRAN LITE, your cholesterol level should begin to decrease. Treatment with QUESTRAN LITE should be continued to sustain the cholesterol reduction. Blood levels of triglycerides (a group of fats) should be measured periodically to detect whether significant changes have occurred.

IF YOUR CHOLESTEROL LEVELS ARE NOT SUFFICIENTLY LOWERED DURING TREATMENT WITH QUESTRAN LITE, TREATMENT WITH QUESTRAN LITE SHOULD BE DISCONTINUED.

Extended use of QUESTRAN LITE at high doses may produce a condition called hyperchloraemic acidosis (increased levels of acid in the blood). This condition is more likely to occur in younger and smaller patients, where the relative dosage may be higher as well as in patients with renal impairment.

QUESTRAN LITE may result in or worsen constipation, or related conditions, such as haemorrhoids. If you suffer from constipation, your dosage of QUESTRAN LITE should be decreased, since it may produce impaction (blockage of the intestines, owing to a solid mass of faeces). If you suffer from a condition called coronary artery disease (heart disease), your dose of QUESTRAN LITE should be adjusted to prevent the occurrence of constipation.

Long term (chronic) use of QUESTRAN LITE may result in an increased bleeding tendency as a result of reduced levels of vitamin K in your body. Should this occur, it can be treated by the administration of injectable vitamin K; recurrences can be prevented by oral administration of vitamin K. Reduced levels of blood folate levels may occur during treatment with QUESTRAN LITE. If this occurs, folic acid supplementation should be considered.

QUESTRAN LITE should be used with caution in patients with peptic ulcers (stomach or intestine ulcers) or with a history of peptic ulcer disease, as it might aggravate or activate this condition.

If you have diarrhoea, body fluid and electrolyte (minerals in your blood) levels may become decreased. Administration of suitable fluids and electrolyte replacements are the most important measure.

To minimise side effects, you will usually start with a single dose of QUESTRAN LITE per day and increase it slowly until you are taking the full number of sachets as prescribed by your doctor. Side effects usually reduce over time.

Other medicines and QUESTRAN LITE

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Any other medicines should be taken at least 1 hour before you take your dose of QUESTRAN LITE or 4 – 6 hours after you have taken your dose of QUESTRAN LITE. The reason for this is because QUESTRAN LITE may change the effects of other medicines by stopping them from working as they should.

QUESTRAN LITE may also stay in the digestive system and can stop or reduce the quantities of other medicines absorbed by the body

When taken together, QUESTRAN LITE may delay or reduce the absorption of oral medicines

The discontinuation of QUESTRAN LITE can be hazardous to your health if the dose of a potentially toxic medicine such as digoxin has been changed to a maintenance level while you were taking QUESTRAN LITE.

If you are taking medicine for which the dose has been adjusted when you started taking QUESTRAN LITE, consult your doctor before you stop taking QUESTRAN LITE, as the dosage of your other medicines may need to be adjusted – particularly if you are taking digoxin.

QUESTRAN LITE may affect the absorption and elimination of medicines, which undergo enterohepatic recirculation (reabsorption of the medicine after it passed through the liver), e.g., oestrogens (a hormone).

QUESTRAN LITE in combination with spironolactone (a tablet that reduces water in the body) may increase the potential for the development of too much blood acidity.

QUESTRAN LITE may interfere with normal fat absorption, resulting in the reduced absorption of fat-soluble vitamins, such as vitamins A, D and K. If you are taking QUESTRAN LITE for long, continuous periods, your doctor may suggest that you take a vitamin supplement.

QUESTRAN LITE can have interactions with the following medicine:

- medicine for heart problems such as amiodarone, digoxin, propranolol
- medicine to treat epilepsy (phenobarbitone, valproate)
- medicine to treat bacterial infections (penicillin G, tetracycline, vancomycin)
- medicine to treat gallstones and lower cholesterol (ursodeoxycholic acid)
- medicine that lower cholesterol (ezetimibe)
- ethinylestradiol (combined hormonal contraceptive).
- anticoagulants used to thin blood (phenprocoumon, warfarin)
- medicine to treat rheumatoid arthritis (leflunomide)
- medicine that suppresses the immune system (mycophenolate, methotrexate)
- medicine to treat inflammation (acetylsalicylic acid, diclofenac, meloxicam, piroxicam, sulindac, tenoxicam)
- furosemide, spironolactone, chlorothiazide, hydrochlorothiazide – medicines that increase the amount of urine you produce
- medicine to treat thyroid problems (levothyroxine, liothyronine, thyroid extract)

Taking QUESTRAN LITE with food and drink:

The suggested time of administration is mealtime, but this may be modified to avoid interference with the absorption of other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking QUESTRAN LITE.

The safety of QUESTRAN LITE in pregnancy and lactation has not been established. QUESTRAN LITE may interfere with the absorption of fat-soluble vitamins, which may have a negative effect on your foetus.

Driving and using machines

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

QUESTRAN LITE contains aspartame and propylene glycol

This medicine contains 30 mg aspartame in each sachet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains 32,5 mg propylene glycol in each sachet. If QUESTRAN LITE has been prescribed for 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 you or your child weigh less than 4 kg or have liver or kidney disease, if you are pregnant or breast-feeding, do not take/administer this medicine unless recommended by your doctor. Your doctor may perform extra checks while you are taking/administering this medicine.

3. How to take QUESTRAN LITE

Do not share medicines prescribed for you with any other person.

Always take QUESTRAN LITE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with QUESTRAN LITE will last. If you have the impression that the effect of QUESTRAN LITE is too strong or too weak, talk to your doctor or pharmacist.

To lower cholesterol levels:

The usual QUESTRAN LITE dose is one 4 g sachet once or twice daily. The dose can be increased to 8 g (two sachets) in the morning and in the evening. If necessary, your dose may be gradually increased to a maximum of 24 g (6 sachets) per day. Although the recommended dosing schedule is twice daily, QUESTRAN LITE may be administered in 1-4 doses per day. You should not take more than 24 g (6 sachets) of QUESTRAN LITE per day, as it may interfere with your normal fat absorption. The suggested time of administration is mealtime, but this may be modified to avoid interference with the absorption of other medicines.

To relieve itching:

The usual QUESTRAN LITE dose is one or two sachets each day.

To manage diarrhoea:

The usual QUESTRAN LITE dose is 1 sachet three times a day. Your doctor may adjust your dose as required.

If you are being treated for diarrhoea, ensure that you are drinking sufficient quantities of fluids. Consult your doctor, pharmacist or other healthcare professional for advice.

If you are taking QUESTRAN LITE for diarrhoea, you should see a response within 3 days of taking the medicine. If you have not seen a response within 3 days, please consult your doctor, pharmacist or other healthcare professional for advice, as alternative treatment may have to be initiated.

How to make up QUESTRAN LITE sachets:

QUESTRAN LITE SHOULD NOT BE TAKEN IN ITS DRY FORM. ALWAYS MIX QUESTRAN LITE WITH WATER OR OTHER FLUIDS BEFORE TAKING IT.

1. The contents of one sachet should be sprinkled evenly on to 115 - 170 ml of water or a beverage, such as milk, fruit juice or broth. Use more water for two sachets (200 – 300 ml).
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 LITE may also be used with pulpy fruits, such as apple sauce or crushed pineapple.

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

If you take more QUESTRAN LITE than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

The greatest harm would be possible obstruction of the stomach and/or intestines. Other possible side effects may include constipation, abdominal discomfort, flatulence (wind), nausea, vomiting, diarrhoea, heartburn, indigestion and steatorrhoea (fat in your faeces), biliary colic (gallbladder pain resulting from gall stones), rash and irritation of the skin, tongue and the area around the anus.

If you forget to take QUESTRAN LITE

If you miss a dose, 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 the forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

QUESTRAN LITE can have side effects.

Not all side effects reported for QUESTRAN LITE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking QUESTRAN LITE, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking QUESTRAN LITE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to QUESTRAN LITE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- obstruction of the intestines (being unable to defecate)
- a tendency to bleed (this could be as a result of low levels of Vitamin K in your body)
- increased blood acidity in children (your doctor will conduct tests to determine this)
- biliary colic (a type of pain in the gallbladder resulting from gall stones)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- constipation

Less frequent side effects

- night blindness (this could be as a result of low levels of Vitamin A in your body)
- Intestinal obstruction

Frequency unknown

- bleeding tendencies due to Vitamin K deficiency
- vitamin A (associated with impaired vision) and D (associated with feeling very tired) deficiency
- the loss of too much sodium bicarbonate from the body (associated with faster heartbeat, feeling very tired)
- diarrhoea
- abdominal discomfort, flatulence (wind)
- dull pain in the middle to upper right area of the abdomen due to a gallstone that blocks the bile duct (biliary colic)
- gallstones
- steatorrhoea (fat in your faeces)
- nausea, vomiting
- heartburn, indigestion
- anorexia (weight loss)
- skin irritation, rash
- irritation of your tongue
- irritation of the area around the anus
- osteoporosis (weak and brittle bones)

The following side effects, which may not be medicine related, were reported in patients taking QUESTRAN LITE:

- decreased or increased blood clotting time
- ecchymoses (bleeding underneath the skin)
- anaemia (low levels of iron in your blood)
- headache
- feeling anxious
- dizziness and disorientation
- fatigue (feeling tired) or feeling sleepy
- tinnitus (ringing in the ears)
- syncope (fainting)
- femoral nerve pain (pain in your upper leg)
- paraesthesia (pins and needles of the extremities)
- uveitis (inflammation of the eye)
- asthma, wheezing, shortness of breath
- breaking wind
- gastrointestinal-rectal bleeding, black stools, haemorrhoidal bleeding, bleeding from known duodenal ulcer (ulcer in the intestine)
- ulcer attack
- rectal pain
- difficulty to swallow, hiccups
- sour taste
- dental bleeding, tooth decay
- pancreatitis (inflammation of the pancreas)
- diverticulitis (inflammation of the bowel)
- urticaria (hives)
- swollen glands
- oedema (swelling)

- backache, muscle and joint pains, arthritis
- weight loss or gain
- haematuria (blood in urine), dysuria (painful or difficult urination), burnt odour to urine, diuresis (increased urination)
- increased libido (sex drive)
- liver function test abnormalities

Large doses of QUESTRAN LITE may cause constipation.

After using QUESTRAN LITE for a long time a few patients have experienced unusual tiredness and rapid or deep breathing.

Long-term treatment with high doses of QUESTRAN LITE may reduce the body's ability to absorb fat-soluble vitamins from the diet, including vitamins A, D and K. Your doctor may suggest that you take a vitamin supplement.

If any of the side effects become 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 side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

5. How to store QUESTRAN LITE

QUESTRAN LITE should be stored at or below 25 °C.

Store all medicines out of reach of children.

Do not use after the expiry date printed on the sachet.

Return unused or expired medicine to the pharmacy.

Do not dispose of unused medicine in drains or sewerage systems.

6. Contents of the pack and other information

What QUESTRAN LITE contains

QUESTRAN LITE contains 4 g of anhydrous colestyramine per sachet.

The other ingredients are:

Each 4 g sachet contains 16,8 mg phenylalanine from aspartame, as sweetener.

Also contains citric acid, colloidal anhydrous silica, orange juice flavour, propylene glycol alginate and xanthum gum.

What QUESTRAN LITE looks like and contents of the pack

QUESTRAN LITE comes in the form of a powder packed in a sachet. QUESTRAN LITE is available in a 4 g sachet and is supplied in packs of 50 sachets.

QUESTRAN LITE is an off-white fine powder with a faint orange odour.

Holder of certificate of registration

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** Authorised user of the trademark QUESTRAN.*