Package leaflet: Information for the patient Colestyramine 4 g 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

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

1. What COLESTYRAMINE is and what it is used for

This medicine contains the active substance colestyramine. Each sachet of this medicine contains 4 g of colestyramine.

Colestyramine belongs to a group of medicines called bile acid binding resins.

COLESTYRAMINE 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.

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

2. What you need to know before you take COLESTYRAMINE

Do not take COLESTYRAMINE:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking COLESTYRAMINE if:

- you are diabetic as COLESTYRAMINE contains sucrose.
- you are in a long-term treatment with high doses of COLESTYRAMINE as it 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.
- 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.
- you receive long-term treatment, as this can cause disturbances of the acid-base balance ("hyperchloraemic acidosis"), especially if you are young and light as well as if you are suffering from renal dysfunction.
- you suffer from constipation.

Children

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

Other medicines and COLESTYRAMINE

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 COLESTYRAMINE.

Any other medicines should be taken at least 1 hour before you take your dose of COLESTYRAMINE or 4-6 hours after you have taken your dose of COLESTYRAMINE. This is because COLESTYRAMINE may change the effects of other medicines by stopping them from working so well and COLESTYRAMINE preparations can stay in the digestive system and can stop other medicines from being absorbed by the body.

COLESTYRAMINE 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 breast-feeding

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

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

COLESTYRAMINE 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. This should be taken into account in patients with diabetes mellitus.

The sucrose in COLESTYRAMINE may be harmful to the teeth.

This medicine contains 97.5 mg propylene glycol (as alginate) in each sachet. If COLESTYRAMINE 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 suffer from a liver or kidney disease, do not take/give this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How to take COLESTYRAMINE

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 recommended 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 recommended dose is one or two sachets each day.

To manage diarrhoea

The recommended 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.

Do not use this medicine if you suffer from exudative or bloody diarrhoea.

How to make up the sachets

- 1. The content 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.

COLESTYRAMINE can be mixed with water, fruit juice, skimmed milk, thin soups or fruit smoothies or sauces (e.g. apple sauce). COLESTYRAMINE should be taken at mealtimes, but if you are taking any other medicines, it is important that they are taken at a different time to your dose of COLESTYRAMINE (see information above "Other medicines and COLESTYRAMINE").

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 COLESTYRAMINE 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 COLESTYRAMINE

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 the forgotten dose.

If you stop using COLESTYRAMINE

You should not suddenly stop taking COLESTYRAMINE.

Discontinuing COLESTYRAMINE may pose a hazard to you if a potentially toxic drug such as digitalis (a medicine for heart failure) has been administered in such a way that it has an adequate effect while taking colestyramine. In addition, oral blood thinners may have an increased effect after COLESTYRAMINE has been deposited.

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. This is very common (may affect more than 1 in 10 people). 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:

Uncommon side effects (may affect up to 1 in 100 people)

- bloatedness.
- wind (flatulence),
- feeling sick (nausea) or vomiting,
- diarrhoea,
- heartburn,
- anorexia, weight loss or gain,
- indigestion (dyspepsia),
- problems with your body's ability to absorb food correctly leading to grey, bulky or smelly stools (steatorrhea),
- increased tendency to bleed, which may also be seen with vitamin D, vitamin K or vitamin A deficiency (which may rarely result in night blindness),
- increased level of chloride in the blood (hyperchloremic acidosis) especially in children and patients with renal dysfunction,
- thin or brittle bones (osteoporosis),
- rash, itching, irritation of skin, tongue or around the anus.

Rare side effects (may affect up to 1 in 1,000 people)

- reports of obstruction of the intestine have been seen.

Side effects occurring in unknown number of patients

- anaemia,
- oedema.
- acute abdominal pain combined with nausea/vomiting with general feeling of illness (acute abdominal symptom complex), belching,
- joint inflammation, backage,
- storage of calcium in the gall bladder, abnormal smelling urine.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store COLESTYRAMINE

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

Do not store above 30°C.

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 COLESTYRAMINE contains

- The active substance is colestyramine. This medicine contains 4 g colestyramine per sachet.
- The other ingredients are acacia, citric acid anhydrous, orange juice flavour, polysorbate 80, propylene glycol alginate, sucrose.

What COLESTYRAMINE looks like and contents of the pack

COLESTYRAMINE 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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