

PINK BOX SHOWS POSITION OF BRAILLE

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Oral use
Tablets should be taken with liquid and with a meal.
Read the package leaflet before use.

Each tablet contains 625 mg of colesevelam (as hydrochloride).

Keep out of the sight and reach of children.

Keep the bottle tightly closed in order to protect from moisture.

Colesevelam Hydrochloride

625 mg film-coated tablets

Colesevelam

180 film-coated tablets

POM

5 060499 391237

Once opened, use within 45 days.
Use by: / /

Medicinal product subject to medical prescription.
PLGB 45043/0064

Neon Healthcare Ltd.
8 The Chase, John Tate Road,
Hertford, SG13 7NN, UK
UK Only

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Package leaflet: Information for the user

Colesevelam Hydrochloride 625 mg film-coated tablets
Colesevelam

Read all of this leaflet carefully before you start using 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.

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

1. What Colesevelam is and what it is used for

Colesevelam contains the active substance colesevelam (as hydrochloride). Taking Colesevelam helps to lower the level of cholesterol in your blood. Your doctor should only give you Colesevelam if a diet low in fat and cholesterol did not work well enough on its own.

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Colesevelam works in your intestinal system by binding bile acids produced by your liver and carrying the bile acids out of your body with your faeces. This prevents your body from recycling the bile acids from your intestines in the usual way. Without the recycling process, your liver has to make additional bile acids. Your liver uses cholesterol from your blood to do this, which lowers the level of cholesterol in your blood.

Colesevelam is prescribed to treat a condition known as primary hypercholesterolaemia (when cholesterol in the blood is elevated) in adults.
- Colesevelam may be prescribed on its own in addition to a diet low in fat and cholesterol when treatment with a statin (a class of cholesterol-lowering medicines that work in the liver) is inappropriate or not well tolerated.
- Colesevelam may be used together with a statin and the diet low in fat and cholesterol when patients are not appropriately controlled by the statin on its own.
- Colesevelam may also be used together with ezetimibe (a cholesterol-lowering

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medicine that works by reducing cholesterol absorption from the gut), with or without a statin.

2. What you need to know before you take Colesevelam

Do not take Colesevelam:
- if you are allergic to colesevelam or to any of the other ingredients of this medicine (listed in section 6)
- if you have a blockage in your intestines or bile ducts (tubes that carry bile)

If you are prescribed Colesevelam and any other medicine together you must also read the patient information leaflet that comes with that particular medicine before you start to take your medicine.

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Warnings and precautions
Talk to your doctor or pharmacist before taking Colesevelam
- if your triglyceride levels (a blood fat) are greater than 3.4 mmol/L
- if you have difficulty in swallowing, or have a major stomach or intestinal disorder
- if you suffer from constipation, as Colesevelam may induce or worsen this condition. This is especially important for patients with coronary heart disease and angina pectoris.

If you think any of these apply to you, you should inform your doctor or pharmacist before taking Colesevelam.

Before starting therapy with Colesevelam, your physician should make sure that certain conditions do not contribute to your elevated cholesterol levels. These could include poorly controlled diabetes, untreated hypothyroidism (low levels of thyroid hormone for which no treatment is being given currently), proteins in urine (nephrotic syndrome),

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altered protein levels in the blood (dysproteinaemias), and blockage of the bile transport to your gall bladder (obstructive liver disease).

Children and adolescents
The safety and efficacy in children (below the age of 18 years) has not been studied. Therefore, Colesevelam is not recommended for use in this population.

Other medicines and Colesevelam
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
If your doctor suspects that Colesevelam may have an effect on the absorption of the other medication, you may be advised to take Colesevelam at least 4 hours before or at least 4 hours after taking the other medication. If you need to take other medicines more than once a day, remember that your Colesevelam tablets can be taken once a day.

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Colesevelam may affect the way in which the following medicines work:
- Anticoagulant therapy (medicines, such as warfarin, used to thin blood). If you are taking anticoagulant therapy you should consult with your physician to closely monitor anticoagulation levels, as Colesevelam may affect the absorption of vitamin K and therefore interfere with the activity of warfarin.
- Thyroid replacement therapy (medicines, such as thyroxine or levothyroxine, used to treat low thyroid hormone levels)
- Oral contraceptives (medicines to prevent pregnancy)
  It is important you take Colesevelam at least 4 hours after you take the oral contraceptive to ensure that the effectiveness of the contraceptive is not affected.
- Verapamil or olmesartan (medicines used to treat high blood pressure). It is important that you take olmesartan at least 4 hours before you take Colesevelam.
- Antidiabetic medications (medicines used to treat diabetes, such as metformin extended-release (ER) tablets, glimepiride, glipizide, pioglitazone, repaglinide or

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glyburide). If you are taking medicines for diabetes, you should consult with your physician so that you can be closely monitored. It is important that you take glimepiride and glipizide at least 4 hours before you take Colesevelam.
- Anti-epileptic medicines (medicines, such as phenytoin, used to treat epilepsy).
- Ciclosporin (a medicine used to suppress the immune system).
- Ursodeoxycholic acid (a medicine used to dissolve gallstones or treat specific chronic liver diseases).

If you are going to take Colesevelam and one of these medicines, your doctor may want to do tests to make sure that Colesevelam does not interfere with these medicines.

Additionally, if you have any condition that could cause you to have a deficiency of vitamins A, D, E or K, your doctor may want to check your vitamin levels periodically while you are taking Colesevelam. If necessary, your doctor may advise you to take vitamin supplements.

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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 or pharmacist for advice before taking this medicine.

If you are prescribed Colesevelam and a statin together it is important that you tell your doctor if you are pregnant or if you are planning to become pregnant because statins must not be used during pregnancy; the patient information leaflet that comes with that particular statin should be consulted.
Tell your doctor if you are breast-feeding. Your doctor may stop your medicine.

Driving and using machines
Your ability to drive or operate machines is not affected by taking Colesevelam tablets.

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3. How to take Colesevelam

Before starting therapy with Colesevelam, you should be advised to follow a cholesterol-lowering diet and you should continue this diet during treatment.

Always take Colesevelam exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure. As described in Section 2, if you will be taking Colesevelam along with another medicine it is possible that your doctor will advise you to take Colesevelam at least 4 hours before or at least 4 hours after taking the other medicine. If you take a medicine called either Neoral® or ciclosporin, please ensure to take it with Colesevelam in a consistent pattern over the day; either always together or always separate for a set number of hours.

You should take your Colesevelam tablets with food and liquid.
The tablets should be swallowed whole. Do not break, crush or chew the tablets.

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Combination therapy:
The recommended dose for Colesevelam, when used with a statin or ezetimibe or both together, is 4 to 6 tablets a day by mouth. Your doctor may tell you to take the Colesevelam dose either once a day or twice a day; in either case Colesevelam should be taken with a meal. The dosing of the statin and the ezetimibe should follow the instructions for that particular medicine. The medicines may be taken at the same time or at separate times according to what your doctor has prescribed.

Monotherapy:
The recommended dose for Colesevelam is 3 tablets taken twice a day with meals or 6 tablets a day with a meal. Your doctor may increase your dose to 7 tablets per day.

If you take more Colesevelam than you should
Please contact your doctor. Constipation or bloating could occur.

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If you forget to take Colesevelam
You may take your dose with a later meal, but never take in one day more than the total number of tablets that your doctor has prescribed to you in a single day.

If you stop taking Colesevelam
Your cholesterol may increase to the level it was before treatment was started.

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.

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The following side effects have been reported in patients taking Colesevelam:
Very common (may affect more than 1 in 10 people): flatulence (wind), constipation.
Common (may affect up to 1 in 10 people): vomiting, diarrhoea, indigestion, abdominal pain, abnormal stools, feeling sick, bloating, headache, raised levels of triglycerides (fats) in your blood.
Uncommon (may affect up to 1 in 100 people): muscle pain, raised levels of liver enzymes in your blood, difficulty in swallowing.
Very rare (may affect up to 1 in 10,000 people): inflammation of the pancreas.
Not known (frequency cannot be estimated from the available data): blockage of the intestines (which can increase among patients with a history of blockage of the intestines or intestinal removal).

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Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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/yelowcard 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.

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5. How to store Colesevelam

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and bottle label after "EXP"

Keep the bottle tightly closed in order to protect from moisture.
Once opened, use within 45 days.
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 to protect the environment.

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6. Contents of the pack and other information

What Colesevelam contains

- The active substance is colesevelam (as hydrochloride). Each tablet contains 625 mg colesevelam.

- The other ingredients (excipients) are:

Tablet core:
Microcrystalline cellulose (E460)
Silica colloidal anhydrous
Magnesium stearate
Purified water

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Film-coating:
Hypromellose (E464)
Diacetylated monoglycerides

Printing ink:
Iron oxide black (E172)
Hypromellose (E464)
Propylene glycol

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What Colesevelam looks like and contents of the pack

Colesevelam tablets are off-white, capsule-shaped film-coated tablets and imprinted with 'C625' on one side. The tablets are packed in plastic bottles with child resistant closures. Pack sizes are: 180 (1 x 180) tablets.

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Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder
Neon Healthcare Ltd.
8 The Chase,
John Tate Road,
Hertford,
SG13 7NN
United Kingdom

Manufacturer
Cheplapharm Arzneimittel GmbH, Ziegelhof 23-24, 17489 Greifswald, Germany

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Oral use
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