

Package leaflet: Information for the user

Colestid® granules for oral suspension 5 g *colestipol hydrochloride*

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

1. What Colestid Granules is and what it is used for

Colestid Granules is a 'lipid lowering agent'. This medicine contains colestipol hydrochloride which is one of a group of medicines called bile acid sequestrants.

Colestid Granules is used to help lower the level of cholesterol in your blood. Your doctor will have recommended a special diet to you in order to help you lose weight since this is very important in lowering your cholesterol levels. Your doctor has given you Colestid Granules since the diet on its own is not lowering your cholesterol enough. It is still very important that you follow your special diet even when taking Colestid Granules. You can find out more about cholesterol from The British Heart Foundation whose address is given at the end of this leaflet.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Colestid Granules

Do not take Colestid Granules:

- if you are allergic (hypersensitive) to colestipol hydrochloride or any of the other ingredients of Colestid Granules (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Colestid Granules if you have:

- an under-active thyroid gland
- nephrotic syndrome (a kidney problem where you get protein in your urine and too much fluid collecting in your body)
- too much or too little protein in your blood
- liver problems e.g. jaundice
- diabetes

Other medicines and Colestid Granules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

There are some medicines that may interact with Colestid Granules and it can affect the way they work.

It is especially important to tell your doctor if you are taking the following medicines:

- heart drugs e.g. digoxin, digitoxin
- beta-blockers e.g. propranolol - for high blood pressure, angina, migraine or anxiety symptoms
- water tablets ('diuretics') e.g. chlorothiazide or furosemide - usually for heart or kidney problems
- antibiotics e.g. tetracycline hydrochloride and penicillin G
- another cholesterol-lowering medicine called gemfibrozil
- Immune-suppressants e.g. mycophenolate mofetil

Your doctor may need to change your dose of these medicines. If you are taking propranolol, your doctor will need to check your dose when you start taking Colestid Granules and also when you stop.

Pregnancy and breast-feeding and fertility

If you are pregnant, 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. Your doctor may stop your treatment.

Driving and using machines

Your ability to drive or operate machines is not affected by taking Colestid Granules.

3. How to take Colestid Granules

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

Colestid Granules must not be taken as a dry powder and must be mixed with a drink or taken with liquid food. The Colestid Granules should be mixed thoroughly with at least 100 ml of water or another still drink such as orange juice or skimmed milk. Alternatively, Colestid Granules can be sprinkled on soup or cereal or mixed with pulpy fruit such as grapefruit or yoghurt, provided that there is at least 100 ml or more of liquid.

Your doctor will advise you on the amount of Colestid Granules you should take, and when.

Most people start by taking one to two sachets of Colestid Granules per day. Your doctor may increase your dose each month until your cholesterol reaches the best level for you. Do not change the number of sachets you take unless your doctor tells you to. Do not take more than 6 sachets (30 grams) a day. If you are prescribed more than two sachets per day, it may be preferable to take Colestid Granules as two separate doses, leaving several hours between e.g. with breakfast and an evening meal.

Taking Colestid with other medicines

If you have other medicines to take, make sure you take them at least one hour before or four hours after your Colestid Granules, except if you are taking gemfibrozil, take this at least two hours before or after your Colestid Granules.

You may have to take Colestid Granules every day for a long time. It is important that you stick to your recommended diet as well as taking your Colestid Granules.

Colestid Granules does not actually dissolve and it therefore has a "gritty" texture, especially if it is not well mixed with the liquid you are using. The "grittiness" of Colestid Granules is much more obvious in "dilute" drinks such as water or fruit juice. In thicker mixtures such as muesli with milk, you may not notice Colestid Granules at all. Some people mix up Colestid Granules the night before to improve results.

Use in children and adolescents

Colestid Granules will not normally be given to children. Ask your doctor for more information if they have prescribed Colestid Granules for a child in your care. If children or young adults are given this medicine, your doctor will need to check their growth and development regularly.

If you take more Colestid Granules than you should

Never take more Colestid Granules than your doctor has told you. If you do, tell your doctor because you may get constipation.

If you forget to take Colestid Granules

Don't worry. Take your next sachet (or sachets) at the usual time.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Colestid Granules

Do not stop taking your tablets or alter the dose you are currently taking without seeing your doctor first.

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 everyone gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine:

- severe constipation, which may cause a blockage in your colon. If this happens you might need some treatment like an enema, to relieve the blockage. Constipation can make piles (haemorrhoids) worse and you may notice blood in your stools.
- headaches, some of which may feel quite severe (migraine, sinus headache)

Tell your doctor if you experience any of the following side effects and they do not go away:

Very common (may affect more than 1 in 10 people)

- constipation, which is usually mild and does not last for long. Eating more fibre and drinking plenty of fluid usually helps
- stomach discomfort

Common (may affect up to 1 in 10 people)

- belching
- wind
- nausea, feeling sick
- sickness or diarrhoea
- rash
- indigestion
- feeling bloated
- aches and pains in your joints and muscles, especially your fingers and toes. You may also feel backache.
- feeling tired

Uncommon: (may affect up to 1 in 100 people)

- loss of appetite (not feel like eating)
- difficulty sleeping
- feeling dizzy and light-headed
- stomach ulcers and bleeding stomach ulcers. These will cause severe stomach pains and if these start to bleed you may pass very dark stools or bring up blood if you are sick
- inflammation of the gall bladder, gallstones or yellowish skin.
- chest pain, discomfort or tightness (angina pectoris), fast heart beat (tachycardia).
- shortness of breath, or breathing difficulty
- itchy skin or hives, inflammation of the skin
- increased or abnormal liver enzymes (alanine aminotransferase increased, aspartate, aminotransferase increased)
- increase in blood alkaline phosphatase (a certain substance in the blood)
- swelling of the ankles, feet or fingers (oedema peripheral)
- feeling weak

Colestid Granules affects the way that your body absorbs fats and some 'fat-soluble' vitamins (A, D, E and K). Your doctor may give you a vitamin supplement if they think this could be happening.

The levels of some fats and enzymes in your blood may rise. This is usually temporary.

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

5. How to store Colestid Granules

Keep out of the sight and reach of children.

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 the month.

Do not store above 25°C.

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 Colestid Granules contains

- The active substance is colestipol hydrochloride. Each 7.5g sachet contains 5g of colestipol hydrochloride.
- The other ingredient is Colloidal Anhydrous Silica.

What Colestid Granules looks like and contents of the pack

- Colestid Granules are light yellow granules for oral suspension.
- Colestid Granules come in cartons of 30 sachets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ

Manufacturer

FARMEA
10 rue Bouché Thomas
Zac Sud d'Orgemont
49007 Angers Cedex
France

Company Contact Address

For further information on this medicine, please contact Medical Information at Pfizer Limited, Walton Oaks, Tadworth, Surrey, Tel: +44 1304 616161

More information about cholesterol

If you would like any more information about changing your lifestyle to lower your cholesterol you can contact:

The British Heart Foundation, Greater London House, 180 Hampstead Road, London, NW1 7AW
Tel: +44 20 7935 0185

This leaflet was last revised in 10/2017

Ref CL 16_0