

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Colestid® Granules



Each sachet contains: colestipol hydrochloride 5 g
For the list of inactive ingredients and allergens, see section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Colestid® lowers the blood cholesterol level in conjunction with controlled diet.

Therapeutic group: bile acid sequestrant.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings regarding use of the medicine
Before treatment with Colestid®, tell your doctor if:

- You have an under-active thyroid gland.
- You have nephrotic syndrome (a kidney problem causing appearance of protein in the urine and accumulation of fluid in the body).
- You have too much or too little protein in the blood.
- You have liver problems e.g. jaundice.
- You have diabetes.

Children and adolescents

This medicine will not normally be given to children. Consult your doctor if the medicine has been prescribed for your child. If the medicine has been prescribed for children or young adults, the doctor will need to monitor their growth and development regularly.

Drug interactions

If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Particularly if you are taking:

- heart medicines e.g. digoxin and digitoxin.
- beta-blockers e.g. propranolol for treatment of hypertension, angina, migraine or anxiety symptoms.
- diuretics e.g. chlorothiazide or furosemide usually used for heart or kidney problems.
- antibiotics e.g. tetracycline hydrochloride and penicillin G.
- gemfibrozil - another cholesterol-lowering medicine.
- immunosuppressants e.g. mycophenolate mofetil.

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

Using this medicine and food

The medicine must not be taken as a dry powder, but must be mixed with a drink or liquid food (see section "How to use this medicine").

Pregnancy, breastfeeding, and fertility

If you are pregnant, breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine. Your doctor may stop your treatment.

Driving and using machines

The ability to drive or operate machines is not affected by Colestid®.

3. HOW TO USE THIS MEDICINE?

Always use this preparation according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

Do not exceed the recommended dose.

The medicine must not be taken as a dry powder. It must be mixed with a drink or liquid food. The powder should be mixed thoroughly with at least 100 ml of water or another still drink such as orange juice or skimmed milk. Alternatively, the powder 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 liquid.

The usual starting dose is one or two sachets of Colestid® granules per day. Your doctor may increase your dose each month until your cholesterol level reaches the best level for you. Do not change the number of sachets you take, unless your doctor instructs you to. Do not take more than 6 sachets (30 grams) a day. If you are taking more than two sachets per day, it is preferable to divide them into two separate doses, leaving several hours between the doses, e.g. with breakfast and dinner.

Taking Colestid® with other medicines

If you are taking other medicines, take them at least one hour before or four hours after taking Colestid®, except if you are taking gemfibrozil, which should be taken at least two hours before or two hours after taking Colestid®.

You may have to take Colestid® on a daily basis for a long period. It is important that you adhere to your recommended diet, as well as taking the medicine.

The medicine granules do not dissolve and therefore, the texture obtained is granular, especially if the granules are not well mixed with the liquid used. The granular appearance of the medicine is obvious mainly in "dilute" liquids such as water or fruit juice. In thick mixtures such as muesli with milk, you may not notice the medicine granules at all. Some people mix the medicine the night before to improve the result.

If you take more Colestid® than you should

Do not take more Colestid® than your doctor has instructed you. If you have taken a dose higher than the one prescribed for you, tell your doctor because you may suffer from constipation.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Colestid® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

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

- severe constipation, which may cause blockage of the bowel. If this happens, you might need treatment, like an enema, to relieve the blockage. Constipation can cause worsening of hemorrhoids and you may notice blood in the stool.
- headaches, some of which may be severe (migraine, sinus headaches).

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

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

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

Common side effects (may affect up to 1 in 10 people): belching; wind; nausea; diarrhea; rash; indigestion; feeling bloated; pain in the joints and muscles, especially in fingers and toes. You may also suffer from backaches; feeling tired

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

loss of appetite; difficulty sleeping; feeling dizzy; stomach ulcers and bleeding stomach ulcers that will cause severe abdominal pains. If the ulcers start to bleed, you may pass very dark stools or vomit blood; inflammation of the gallbladder, gallstones or yellowish skin; chest pain, discomfort or tightness (angina pectoris), fast heart beat (tachycardia); shortness of breath or breathing difficulties; itchy skin or hives, inflammation of the skin; increased or abnormal liver enzyme levels (increased level of alanine aminotransferase, increased level of aspartate aminotransferase); increased blood level of alkaline phosphatase (a certain substance in the

blood); swelling of the ankles, feet or fingers (peripheral edema); feeling weak

Colestid® affects the way that your body absorbs fats and some fat-soluble vitamins (A, D, E and K). Your doctor may recommend you to take a vitamin supplement if he thinks this could be happening.

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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25° C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

silica colloidal anhydrous

What the medicine looks like and contents of the pack:

A sachet containing yellow-orange granules. The sachets are packed in packs of 50 sachets.

Registration holder and address:

Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Colestid®: 044-74-23527

Revised in November 2020 in accordance with Ministry of Health guidelines.