COLESTID® Granules for Oral Suspension

Colestipol hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about COLESTID. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking COLESTID against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What COLESTID is used for

What COLESTID does

COLESTID helps to lower blood cholesterol levels. It should be used in conjunction with a low fat diet.

Everyone has cholesterol in their blood. It's a type of blood fat needed by the body for many things, such as building the lining of cells, making bile acids (which help to digest food) and some hormones. However, too much cholesterol can be a problem. COLESTID does not reduce the amount of cholesterol that comes from the fat in food. Therefore, you should also follow a low fat diet and start other measures, such as exercise and weight control.

In most people, there are no symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test.

How COLESTID works

COLESTID contains colestipol hydrochloride which is a kind of resin.

COLESTID works in the intestine by trapping bile acids and preventing them from being reabsorbed.
COLESTID is not absorbed into the body, but passes through the intestine, drawing bile acids out in the process. The decrease in the bile acids recirculation leads to an increase in producing new bile acids by the liver from cholesterol, hence a decrease in cholesterol level in the blood.

Your doctor may have prescribed COLESTID for another reason.

Ask your doctor if you have any questions about why COLESTID has been prescribed for you.

There is no evidence that COLESTID is addictive.

This medicine is available only with a doctor's prescription.

Use in Children

COLESTID is not recommended to be taken by children.

Before you take COLESTID

When you must not take it

Do not take COLESTID if you have an allergy to COLESTID or any medicine containing colestipol hydrochloride, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- · shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take COLESTID if the packaging is torn or shows signs of tampering.

Do not take COLESTID if the expiry date (EXP) printed on the pack has passed.

Ask your doctor if you are not sure whether you should start taking COLESTID.

Before you start to take it

Tell your doctor if:

- 1. if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- 2. if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of taking COLESTID during pregnancy.

3. if you are breast-feeding or intend to breast-feed.

Your doctor will discuss the risks and benefits of taking COLESTID when breast-feeding.

- 4. you have or have had any of the following medical conditions:
- · an underactive thyroid gland
- diabetes
- · kidney or liver disease
- problems with bleeding or bruising
- constipation.
- 5. you are taking any fat soluble vitamins, such as vitamins A, D and K, or folic acid supplements.
- 6. you drink alcohol regularly.

If you have not told your doctor about any of the above, tell them before you take any COLESTID.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by COLESTID or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- propranolol (e,g, INDERAL or DERALIN), digoxin (e.g. LANOXIN), medicines used for treating heart problems
- gemfibrozil (e.g. LOPID or JEZIL), a medicine used to lower cholesterol
- chlorothiazide, hydrochlorothiazide or frusemide, diuretics used to remove fluid from the body, also known as water tablets

- tetracycline or penicillin G, medicines for bacterial infections
- oral phosphate supplements
- mycophenolic acid or mycophenolate mofetil, a medicine used to suppress the immune system.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking COLESTID.

How to take COLESTID

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

The recommended total daily dose is 15 - 30 grams (3 - 6 sachets).

COLESTID granules should be taken in divided doses, two to four times daily.

How to take it

COLESTID should never be taken in its dry form and should always be mixed with a liquid. This is to avoid accidental inhaling or throat discomfort.

Preparing your medicine:

To prepare COLESTID as a liquid, add the granules to one large glass (100 - 150 mL) or more of milk, flavoured milk, soft drink or your favourite fruit juice, such as orange, tomato or pineapple juice. It can also be added to water, but other liquids taste better.

Stir the mixture until the granules are completely mixed (COLESTID will not dissolve in the liquid). Rinse the glass with a small amount of the same liquid, to make sure all the COLESTID is taken.

COLESTID may also be taken with milk in hot or regular breakfast cereals, or even mixed in soups that have a high liquid content, such as tomato or chicken noodle soup. COLESTID is most palatable when added to pulpy fruits, such as pineapple, pears, peaches or fruit cocktail.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you are taking any other medicines, they should be taken one hour before or four hours after COLESTID.

How long to take it

COLESTID helps lower your cholesterol. It does not cure your condition. Therefore, you must continue to take it as directed by your doctor if you expect to lower your cholesterol and keep it down. You may have to take cholesterol-lowering medicine for the rest of your life. If you stop taking COLESTID, your cholesterol levels may rise again.

Do not stop taking COLESTID suddenly.

Your doctor may need to change the dose of your other medicines if you stop COLESTID, so you should only stop when your doctor tells you to.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much COLESTID. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places handy.

It is important that you do not take more COLESTID than your doctor has prescribed. Overdosage could cause bowel obstruction, however this has never been reported. If you do take more than you have been prescribed, contact your doctor for advice.

If a child accidentally swallows your COLESTID granules, contact your nearest hospital or Poisons Information Centre immediately.

While you are taking COLESTID

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will ask you to have regular blood test. Your liver function will be tested from time to time while you are taking COLESTID to make sure the medicine is working and to prevent unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking COLESTID.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine. If you become pregnant while you are taking COLESTID tell your doctor.

Things you must not do

Do not give COLESTID to anyone else, even if they have the same condition as you.

Do not take COLESTID to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of COLESTID causing liver problems.

Be careful driving or operating machinery until you know how COLESTID affects you.

COLESTID generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, COLESTID may cause dizziness in some people.

Things that would be helpful for your conditions

Lowering high cholesterol can help reduce your chances of having Coronary Heart Disease (CHD). However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking, diabetes, excess weight, family history of CHD, being a male and being a woman who has reached menopause.

Some self help measures suggested below may help your condition and help reduce your chances of having CHD. Talk to your doctor, pharmacist, or dietician about these measures and for more information.

- Diet continue the low fat diet recommended by your doctor, dietician or pharmacist.
- Weight your doctor may advise you to lose weight if you are overweight.
- Exercise make exercise a part of your routine - walking is good.
 Ask your doctor for advice before starting exercise.
- Smoking smoking increases the risk of you suffering from heart problems. Your doctor will advise you to stop smoking.
- Alcohol excessive alcohol intake can raise your cholesterol levels or affect your liver function, which could increase the chance of you getting unwanted side effects. Your doctor may discuss with you whether you should reduce the amount of alcohol you drink.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COLESTID.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if...

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- constipation
- · abdominal pain
- belching
- gas in the stomach and bowel
- nausea
- vomiting
- diarrhoea
- indigestion
- heartburn
- muscle, joint or back pains
- headache
- migraine
- lightheadedness
- sleeplessness
- skin rash
- · swelling of the hands and feet
- fatigue
- · loss of appetite
- · feeling weak
- feeling anxious

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- fast heart beat
- shortness of breath
- blood in stools
- haemorrhoids
- strong muscle pain
- strong abdominal pain
- sign of liver disease such as yellowing of the skin and eyes and dark coloured urine.

The above list includes serious side effects that may require medical attention. Serious side effects are

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- symptoms of allergy such as skin rash, itching, swelling of the face, lips, mouth, tongue, throat or neck which may cause difficulty in swallowing or breathing
- chest pain.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking COLESTID

Storage

Keep COLESTID in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is good place to store medicines.

Disposal

If your doctor tells you to stop taking the medicine or the sachets have passed their expiry date, ask your pharmacist what to do with any sachets that are left over.

Product Description

What it looks like

Each COLESTID sachet contains pale yellow granules.

COLESTID is available in packs containing 120 foil sachets (4 boxes of 30 sachets).

Ingredients

Each sachet of COLESTID Granules for Oral Suspension contains 5 grams of colestipol hydrochloride as the active ingredient.

COLESTID also contains the following inactive ingredient: silica (silicon dioxide).

COLESTID does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

COLESTID is supplied in Australia by:

Pfizer Australia Pty Ltd ABN 50 008 422 348

38-42 Wharf Road West Ryde NSW 2114 Australia

Toll Free number: 1800 675 229

Australian Registration Number

• AUST R 12283

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