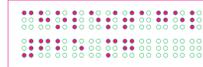


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Previous GMID:	601440
Description:	LABL/INERT/CHL/CS2/SNG/ET1/0 E/UK
Vista Folder #:	2697760
Revision:	1
Market:	Ireland / UK
Language(s):	English
Date:	24 Feb. 2017
Operator:	Alan Aylward
Min Point Size:	9pt
Lot/Batch:	Batch
Expiry:	EXP
ID:	ID
Printing Color:	Black, P-356, P-280
Non-Printing Color:	Yellow, Text Area, Red, Blue, Green
Product Barcode:	EAN13 - 5030045000135
Plant Barcode:	667995
Spec:	Spec 154
Template Ref.:	IE01 PK 4002 (Rev 3)
Dimensions:	58mm x 145mm



**PINK BOX SHOWS POSITION OF BRAILLE**

Braille Reads:  
C h o l e s t a g e l  
No. 6 2 5 m g

**FRONT PAGE**

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

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

Keep out of the sight and reach of children.  
Keep the bottle tightly closed in order to protect from moisture.

**Cholestagel<sup>®</sup>**  
625 mg film-coated tablets  
Colesevelam

180 film-coated tablets

Medicinal product subject to medical prescription.  
EU/1/03/268/004

Genzyme Europe B.V.  
Goimeer 10  
1411 DD Naarden  
The Netherlands

United Kingdom (Ireland): 030045 000135

genzyme  
A SANOFI COMPANY

**PAGE 2**

**Package leaflet: information for the user**

**Cholestagel 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.

**PAGE 3**

**What is in this leaflet:**

- What Cholestagel is and what it is used for
- What you need to know before you take Cholestagel
- How to take Cholestagel
- Possible side effects
- How to store Cholestagel
- Contents of the pack and other information

**1. What Cholestagel is and what it is used for**

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

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Cholestagel 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.

Cholestagel is prescribed to treat a condition known as primary hypercholesterolaemia (when cholesterol in the blood is elevated) in adults.

Cholestagel 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 on the liver) is inappropriate or not well tolerated.

Cholestagel 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.

Cholestagel may also be used together with ezetimibe (a cholesterol-lowering medicine

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

**2. What you need to know before you take Cholestagel**

**Do not take Cholestagel:**

- If you are allergic to colessevelam 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 Cholestagel 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 Cholestagel

- 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 Cholestagel 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 Cholestagel.

Before starting therapy with Cholestagel, 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 (dysproteinemia), 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, Cholestagel is not recommended for use in this population.

**Other medicines and Cholestagel**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If your doctor suspects that Cholestagel may have an effect on the absorption of the other medication, you may be advised to take Cholestagel 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 Cholestagel tablets can be taken once a day.

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Cholestagel 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 Cholestagel 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 Cholestagel at least 4 hours after you take the oral contraceptive to ensure that the effectiveness of the contraceptive is not affected.

Vesapamil or olmesartan (medicines used to treat high blood pressure). It is important that you take olmesartan at least 4 hours before you take Cholestagel.

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 Cholestagel.

- Anti-epileptic medicines (medicines, such as phenytoin, used to treat epilepsy).
- Ciclosporin (a medicine used to suppress the immune system).

Ciclosporin (a medicine used to suppress the immune system) or treat specific chronic liver diseases).

If you are going to take Cholestagel and one of these medicines, your doctor may want to do tests to make sure that Cholestagel 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 Cholestagel. 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 Cholestagel 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 Cholestagel tablets.

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**3. How to take Cholestagel**

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

Always take Cholestagel 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 Cholestagel along with another medicine it is possible that your doctor will advise you to take Cholestagel at least 4 hours before or at least 4 hours after taking the other medicine.

If you take a medicine called either Neoral<sup>®</sup> or ciclosporin, please ensure to take it with Cholestagel in a consistent pattern over the day; either always together or always separate for a set number of hours.

You should take your Cholestagel 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 Cholestagel, 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 Cholestagel dose either once a day or twice a day; in either case Cholestagel 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 Cholestagel 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 Cholestagel than you should**

Please contact your doctor. Constipation or bloating could occur.

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**If you forget to take Cholestagel**

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 Cholestagel**

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 Cholestagel:

**Very common** (may affect more than 1 in 10 people): flatulence (wind), constipation, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

United Kingdom  
You can also report side effects directly via the Yellow Card Scheme at:  
[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

Ireland  
You can also report side effects directly via HPA Pharmacovigilance, Earlsfort Terrace, (RIL - Dublin 2).  
Tel: +353 1 6764971;  
Fax: +353 1 6762517;  
Website: [www.hpra.ie](http://www.hpra.ie);  
E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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Malta  
ADN Reporting, The Medicines Authority,  
Post-Licensing Directorate, 203 Level 3, Rue  
D'Argens, GR-1368 Gzira  
Website: [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)  
E-mail: [postlicensing.medicinesauthority.gov.mt](mailto:postlicensing.medicinesauthority.gov.mt)

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

**5. How to store Cholestagel**

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

**PAGE 17**

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.

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.

**6. Contents of the pack and other information**

**What Cholestagel contains**

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

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The other ingredients (excipients) are:

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

**Film-coating:**  
Hypromellose (E646)  
Diacetylated monoglycerides

**Printing ink:**  
Iron oxide black (E172)  
Hypromellose (E646)  
Propylene glycol

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**What Cholestagel looks like and contents of the pack**

Cholestagel tablets are off-white, capsule-shaped film-coated tablets and imprinted with "C225" on one side. The tablets are packed in plastic bottles with child-resistant closures. Pack sizes are 24 (1 x 24), 100 (2 x 50) and 180 (1 x 180) tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing authorisation holder  
Genzyme Europe B.V., Goimeer 10, 1411 DD Naarden, The Netherlands

Manufacturer  
Genzyme Ireland Ltd., IDA Industrial Park, Old Kilmeaden Road, Waterford, Ireland

**PAGE 20**

**For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.**

**Ireland**  
Sanofi-aventis Ireland Ltd T/A SANOFI  
Tel: +353 (0) 1 4035 600

**Malta**  
Sanofi Malta Ltd  
Tel: +356 21493022

**United Kingdom**  
Sanofi  
Tel: +44 (0) 845 372 7101

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**This leaflet was last revised in 01/2017.**

**Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu/>

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**PAGE 24**

**PAGE 25 - BASE LABEL A**

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**Cholestagel<sup>®</sup>**  
625 mg film-coated tablets  
Colesevelam

180 film-coated tablets

Medicinal product subject to medical prescription.  
EU/1/03/268/004

Genzyme Europe B.V.  
Goimeer 10  
1411 DD Naarden  
The Netherlands

United Kingdom (Ireland): 030045 000135

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**Base Label B (text free)**

STD BOOKLET  
ORAL DOSE

Old Drawing Number	Rev
Drawing Number IE01-PK-4002	3
Tag Number NA	