PART III: CONSUMER INFORMATION

COLESTID[®] Granules (colestipol hydrochloride for oral suspension USP) **COLESTID[®] ORANGE Granules** (colestipol hydrochloride for oral suspension) **COLESTID[®]** Tablets (colestipol hydrochloride tablets)

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about COLESTID. Contact your doctor or pharmacist if you have any questions about this drug.

ABOUT THIS MEDICATION

What the medication is used for:

In addition to a standard diet to lower cholesterol and exercise. COLESTID can be used to reduce the amount of cholesterol in the blood.

Your doctor may also prescribe weight loss while you are taking COLESTID.

Your doctor will put you on a special diet to help lower your cholesterol. Follow the diet while you are taking COLESTID. Taking COLESTID does not replace the need to be on a special diet. It is important for your treatment that you do both.

What it does:

COLESTID works by preventing bile acids from being taken up in the blood.

Bile acids are formed when your body breaks down cholesterol. The medicine in COLESTID acts by trapping bile acids in the bowels. Bile acids trapped by COLESTID pass out of your body instead of going into the blood. When there are less bile acids, your body is forced to break down more cholesterol, which will lower the cholesterol level in your blood.

When it should not be used:

Do not take COLESTID

- if you are allergic (hypersensitive) to colestipol hydrochloride or to any of the other ingredients of COLESTID
- if you have a blockage in your intestines or bile ducts (tubes that carry bile)
- if you have phenylketonuria you should not take ٠ COLESTID ORANGE granules. They contain aspartame. Phenylketonurics are sensitive to the phenylalanine in aspartame.

What the medicinal ingredient is: Colestipol hydrochloride

What the nonmedicinal ingredients are:

COLESTID granules: Colloidal silicon dioxide

COLESTID ORANGE Granules:

Aspartame, beta-carotene, citric acid, glycerine, mannitol, maltol, methyl cellulose, artificial and natural flavor

COLESTID Tablets:

Carnauba wax, cellulose acetate phthalate, colloidal silicon, dioxide, hypromellose, magnesium stearate, povidone, triacetin

What dosage forms it comes in:

COLESTID Granules for oral suspension USP in foil packet. Each packet contains 5g colestipol hydrochloride.

COLESTID ORANGE Granules for oral suspension in foil packet. Each packet contains 5g colestipol hydrochloride.

COLESTID Tablets in bottles. Each tablet contains 1 g of colestipol hydrochloride

WARNINGS AND PRECAUTIONS

BEFORE you use COLESTID talk to your doctor or pharmacist if:

- You have or have had in the past any health • problems as some conditions can affect your cholesterol level and should be treated before you take COLESTID.
- You have dysproteinemia (an abnormality in protein content of the blood, usually in the content of immunoglobulins), diabetes, thyroid, gallbladder, kidney or liver disease
- You have a deficiency of vitamins A, D, or K.
- You are pregnant, if you become pregnant or if you are breastfeeding your baby.
- You are taking other medicines, even medicine • without prescription.
- you have irritable bowel syndrome, diverticulosis and diverticulitis, as these conditions can be influenced by the nonmedicinal ingredient colloidal silicon present in these products

INTERACTIONS WITH THIS MEDICATION

COLESTID can reduce the effect of other medications taken at the same time. Take other medications at least 1 hour before or, wait 4 hours after you take COLESTID before taking other medications

Drugs that may interact with COLESTID include:

- Antibiotics
- Beta-blockers (used to decrease blood pressure)
- Digoxin or digitoxin
- Diuretics (water pills)
- Warfarin (anticoagulant)
- Mycophneolate mofetil (immunosuppressant)

PROPER USE OF THIS MEDICATION

Usual Adult Dose:

COLESTID Granules or COLESTID ORANGE Granules:

5 to 30 g per day once or in divided doses. Usual starting dose is 5 g once or twice a day.

COLESTID Tablets:

2 to 16 g per day once or in divided doses. Usual starting dose is 2 g once or twice a day.

Dosages can be increased at one month intervals. Your doctor will decide the best dosage for you.

Usual dose for Children 10 years and older: Will be determined by the doctor. The lowest dose of the granules is recommended.

COLESTID Granules or COLESTID ORANGE Granules:

Never take COLESTID ORANGE granules USP or COLESTID granules in its dry form, as it can cause you to choke.

A heavy or pulpy juice may reduce the "gritty" feel of the medicine.

Unsweetened juice may make COLESTID taste better.

PREPARATION

Always mix COLESTID with liquids or foods. * For liquids you may choose: water, milk, flavoured drink, juice or any other liquid of your choice.

* For foods you may choose: cereals (hot or cold), soups (avoid chunky soups), yogurt, pudding, cottage cheese or pulpy fruits (crushed pineapple, pears, peaches or fruit cocktail).

Step 1. Add the amount of your dose (packets) of COLESTID to at least 100 mL (3-4 oz) of liquid or food.

Step 2. Stir the medicine until it is evenly mixed. The medicine will not completely dissolve; you will still be able to see the granules.

Step 3. Drink or eat all of the mixture. When you are finished, rinse the glass or bowl with a small amount of liquid that you drink to make sure you have taken all the medicine.

COLESTID Tablets:

Do not cut, chew or crush the tablets.

Swallow COLESTID Tablets whole. Take them with a full glass of liquid. You may choose water, milk, flavoured drink, juice, pop or soda, or any other liquid of your choice.

Take COLESTID Tablets with your meals. If you take COLESTID Tablets more than once a day, take one dose at breakfast or lunch, and a second dose in the evening.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of this medicine, take it as soon as possible. For the rest of the day continue on your regular schedule. But, if you miss a dose and it is almost time for the next dose, do not take the 2 doses together. Take only the dose you should be taking at this time.

Do not take a double dose of COLESTID to make up for missed doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- worsened haemorrhoids and bleeding from haemorrhoids
- nausea, bloating, gas, heartburn, vomiting, loss of appetite,
- headache, anxiety, dizziness, drowsiness,
- fatigue, weakness, insomnia

Call your doctor, if these effects continue or worsen. If you feel any other unusual effects not listed here, see your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and Seek
		Only if severe	In all cases	immediate medical help
Frequency				
Very Common	Constipation		\checkmark	
	Stomach pain		\checkmark	
Common	Diarrhea		\checkmark	
	Joint and muscle pains, back pain		\checkmark	
	Blood in feces		\checkmark	
	Shortness of breath		\checkmark	
	Vertigo		\checkmark	
	Ulcers		\checkmark	
	Skin Reaction: rash		\checkmark	
	Inflammation of the gallbladder, gall stone: symptoms like abdominal pain so intense that you can't sit still or find a comfortable position		V	
Uncommon	Elevated liver enzyme levels		\checkmark	
	Allergic Reaction: symptoms like hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			\checkmark
	Chest pain		\checkmark	
	Rapid heart beats		\checkmark	

This is not a complete list of side effects. For any unexpected effects while taking COLESTID, contact your healthcare professional.

HOW TO STORE IT

Keep out of the sight and reach of children. Store COLESTID Tablets away from heat, direct sunlight and humid places like your bathroom. COLESTID is best kept at room temperature $(15^{\circ}-30^{\circ}C)$ in a dry place.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffectcanada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

http://www.pfizer.ca

or by contacting the sponsor, Pfizer Canada ULC at: 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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