

PART III: CONSUMER INFORMATION

COTAZYM[®] (Pancrelipase Preparations)

This leaflet is part III of a three-part "Product Monograph" published when COTAZYM[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about COTAZYM[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

COTAZYM[®] is used for the treatment of pancreatic insufficiency attributed to cystic fibrosis, chronic pancreatitis, or any other medically defined pancreatic disease that might require pancreatic enzyme therapy, as determined by the doctor.

What it does:

COTAZYM[®] is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis, swelling of the pancreas that lasts a long time (chronic pancreatitis), removal of some or all of the pancreas (pancreatectomy), or other conditions.

COTAZYM[®] may help your body use fats, proteins, and sugars from food. It contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas.

When it should not be used:

COTAZYM[®] should not be used if you:

- have known hypersensitivity to porcine protein, pancreatic enzymes or any excipients; and/or during acute pancreatitis or the acute exacerbation of chronic pancreatitis

What the medicinal ingredient is:

Lipase, amylase, protease, mixed conjugated bile salts and cellulose.

What the important nonmedicinal ingredients are:

Capsule print ink, cellulose acetate phthalate, colloidal silicon dioxide, cornstarch, diethyl phthalate, gelatin, magnesium stearate, povidone, precipitated calcium carbonate, pregelatinized starch, propylene glycol, silicon dioxide, sodium lauryl sulphate, sucrose, talc, titanium dioxide, red food dye (FD&C Red No. 40), yellow food dye (D&C Yellow No. 10).

What dosage forms it comes in:

Capsules containing 10,000 units of lipase, 40,000 units of amylase and 35,000 units of protease (Cotazym[®]).

Enteric coated capsules containing 10,800 units of lipase, 42,000 units of amylase and 45,000 units of protease (Cotazym[®] ECS 8).

Enteric coated capsules containing 25,000 units of lipase, 100,000 units of amylase and 100,000 units of protease (Cotazym[®] ECS 20).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

COTAZYM[®] may increase your chance of having a rare bowel disorder called fibrosing colonopathy. This condition is serious and may require surgery. The risk of having this condition may be reduced by following the dosing instructions that your doctor gave you.

Talk to your doctor about all the drugs you are taking before taking COTAZYM[®].

BEFORE you use COTAZYM[®] talk to your doctor or pharmacist if you:

- Are allergic to pork (pig) products
- Have a history of intestinal blockage or scarring or thickening of your bowel wall (fibrosing colonopathy)
- Have gout, kidney disease, or high blood uric acid (hyperuricemia or hyperuricosuria)
- Have trouble swallowing capsules
- Have any other medical condition
- Are pregnant, plan to become pregnant, are breast-feeding or plan to breast-feed. It is not known if COTAZYM[®] will harm your unborn baby or if COTAZYM[®] passes into your breast milk. Enzymes such as COTAZYM[®] are broken down in your gastrointestinal tract, and thus are not absorbed into the body as intact enzymes.

Tell your doctor all the medications that you take, including prescription and nonprescription drugs, natural health products, vitamins and herbs.

Talk to your doctor if the following occurs while taking COTAZYM[®]:

- stomach area (abdominal) pain
- bloating
- trouble passing stool (having bowel movements)
- nausea, vomiting, or diarrhea

Take COTAZYM[®] exactly as prescribed. Do not take more or less COTAZYM[®] than directed by your doctor.

INTERACTIONS WITH THIS MEDICATION

As with all other pancrelipase lipase preparations, interactions with COTAZYM[®] is possible. Therefore, tell your doctor all

the medications that you take, including prescription and nonprescription drugs, natural health products, vitamins and herbs.

PROPER USE OF THIS MEDICATION

- Take COTAZYM® exactly as prescribed by your healthcare provider.
- You should not switch COTAZYM® with any other pancreatic enzyme product without first talking to your doctor.
- Do not take more capsules in a day than the number your doctor tells you to take (total daily dose).
- Always take COTAZYM® with a meal or snack and enough liquid to swallow COTAZYM® completely. If you eat a lot of meals or snacks in a day, be careful not to go over your total daily dose.
- If the capsules are opened, try to avoid sprinkling them on dairy products such as milk, custard or ice cream.
- Your doctor may change your dose based on the amount of fatty foods you eat or based on your weight.
- Do not crush or chew COTAZYM® capsules or its contents, and do not hold the capsule or capsule contents in your mouth. Crushing, chewing or holding the COTAZYM® capsules in your mouth may cause irritation in your mouth or change the way it works in your body.

Usual dose:

Take 1 to 3 capsules with each meal and 1 capsule with each snack as directed by your doctor.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of pancreatic enzyme preparations including COTAZYM® include the following:

- Blood sugar increase (hyperglycemia) or decrease (hypoglycemia)
- Pain in your stomach (abdominal area)
- Frequent or abnormal bowel movements
- Gas
- Sore throat and cough
- Dizziness
- Vomiting

Other Possible Side Effects

COTAZYM® and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. These pigs may carry viruses. Although it has never been reported, it may be possible for a person to get a viral infection from taking pancreatic enzyme products that come from pigs.

Tell your healthcare professional if you have any side effect that bothers you or does not go away.

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

COTAZYM® may cause serious side effects including:

- **Irritation of the inside of your mouth.** This can happen if COTAZYM® is not swallowed completely.
- **Increase in blood uric acid levels. This may cause worsening of swollen, painful joints (gout) caused by an increase in your blood uric acid levels.**
- **Allergic reactions, including trouble with breathing, skin rashes, or swollen lips.**

Call your doctor right away if you have any of these symptoms.

This is not a complete list of side effects. For any unexpected effects while taking COTAZYM®, contact your doctor or pharmacist.

HOW TO STORE IT

- Store COTAZYM® at room temperature below 25°C.
 - Keep COTAZYM® in a dry place and in the original container.
 - After opening the bottle, keep it closed tightly between uses to protect from moisture.
- Keep COTAZYM® and all medicines out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
 Health Canada
 Postal Locator 0701E
 Ottawa ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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: www.organon.ca or by contacting the sponsor, Organon Canada Inc. at: 1-844-820-5468.

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