

MEDICATION GUIDE
VIOKACE™ (vye-oh-kase)
(pancrelipase)
tablets

Read this Medication Guide before you start taking VIOKACE and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about VIOKACE?

VIOKACE 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.

Call your doctor right away if you have any unusual or severe:

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

Take VIOKACE exactly as prescribed by your doctor. Do not take more or less VIOKACE than directed by your doctor.

What is VIOKACE?

VIOKACE is a prescription medicine used with a proton pump inhibitor medicine (PPI) to treat adults who cannot digest food normally. Adults with swelling of the pancreas that lasts a long time (chronic pancreatitis), or who have had some or all of their pancreas removed (pancreatectomy) may not digest food normally because they do not make enough enzymes or because their enzymes are not released into the bowel (intestine).

VIOKACE contains a mixture of digestive enzymes (including lipases, proteases, and amylases) from pig pancreas.

It is not known if VIOKACE is safe and effective in children. Use of VIOKACE in children may result in poor nutrition and slowing of growth.

What should I tell my doctor before taking VIOKACE?

Before taking VIOKACE, tell your doctor about all your medical conditions, including if you:

- are allergic to pork (pig) products
- have a history of blockage of your intestines, or scarring or thickening of your bowel wall (fibrosing colonopathy)
- have gout, kidney disease, or a condition called high blood uric acid (hyperuricemia)
- have trouble swallowing tablets
- are lactose intolerant

- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if VIOKACE will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VIOKACE passes into your breast milk. You and your doctor should decide if you will take VIOKACE or breastfeed.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, or herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take VIOKACE?

- **Take VIOKACE tablets exactly as your doctor tells you.**
- You should not switch VIOKACE with any other pancreatic enzyme product without first talking to your doctor.
- Do not take more tablets in a day than the number your doctor tells you to take (total daily dose).
- Always take VIOKACE with a meal or a snack and enough liquid to swallow VIOKACE completely. If you eat a lot of meals or snacks in a day, be careful not to go over your total daily dose.
- Your doctor may change your dose based on the amount of fatty foods you eat or based on your weight.
- Your doctor should also prescribe a medicine for you called a proton pump inhibitor (PPI) to decrease stomach acid. VIOKACE should be taken with a PPI to help prevent VIOKACE from breaking down in your stomach.
- Swallow VIOKACE tablets whole. Do not crush or chew the tablets. Be careful to make sure that no VIOKACE is left in your mouth. Crushing, chewing or holding the VIOKACE tablets in your mouth may cause irritation in your mouth, or change the way VIOKACE works in your body..
- If you forget to take VIOKACE, wait until your next meal and take your usual number of tablets. Take your next dose at your usual time. **Do not take two doses at one time.**

What are the possible side effects of VIOKACE?

VIOKACE may cause serious side effects, including:

- See **“What is the most important information I should know about VIOKACE?”**
- **Irritation of the inside of your mouth.** This can happen if VIOKACE 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 levels.
- **Allergic reactions**, including trouble with breathing, skin rashes, or swollen lips.

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

The most common side effects of VIOKACE include:

- you can develop stones that form in your gallbladder and the tubes that carry bile to your small intestines.
- anal itching

Other possible side effects:

VIOKACE 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 doctor if you have any side effect that bothers you or that does not go away.

These are not all the side effects of VIOKACE. For more information ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Aptalis Pharma US, Inc. at 1-800-472-2634.

How should I store VIOKACE?

- Store VIOKACE at room temperature, 68°F to 77°F (20°C to 25°C). Avoid heat.
- Keep VIOKACE in a dry place and in its original container.
- After opening the bottle, keep it closed tightly between uses to protect from moisture.
- The VIOKACE bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). **Do not eat or throw away the desiccant packet.**

Keep VIOKACE and all medicines out of reach of children.

General information about the safe and effective use of VIOKACE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIOKACE for a condition for which it was not prescribed. Do not give VIOKACE to other people to take, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about VIOKACE. If you would like more information, talk to your doctor. You can ask your pharmacist or doctor for information about VIOKACE that is written for healthcare providers.

For more information, go to www.aptalispharma.com or call toll-free 1-800-472-2634.

What are the ingredients in VIOKACE?

Active ingredient: lipase, protease and amylase

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, stearic acid and talc.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Aptalis Pharma US, Inc
22 Inverness Center Parkway
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Manufactured by:

Confab Laboratories, Inc.
St. Hubert, Canada

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