

MEDICATION GUIDE
ULTRESA™ (ul-tres-a)
(pancrelipase)
delayed-release capsules

Read this Medication Guide before you start taking ULTRESA 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 ULTRESA?

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

What is ULTRESA?

ULTRESA 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 or other conditions.

ULTRESA capsules contain a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas.

ULTRESA is safe and effective in children when taken as prescribed by your doctor.

What should I tell my doctor before taking ULTRESA?

Before you take ULTRESA, tell your doctor about all of your medical conditions, including 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 a condition called high blood uric acid (hyperuricemia)

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

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and 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 ULTRESA?

- **Take ULTRESA capsules exactly as your doctor tells you**
- You should not switch ULTRESA 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 ULTRESA with a meal or snack and plenty of fluid. 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.
- **Do not crush or chew the ULTRESA capsules or their contents, and do not hold the capsule or capsule contents in your mouth.** Crushing, chewing or holding the ULTRESA capsules in your mouth may cause irritation in your mouth or change the way ULTRESA works in your body.

Giving ULTRESA to children and adults:

1. You should not divide the capsule contents into small amounts to give small doses of ULTRESA.
2. Swallow ULTRESA capsules whole and take them with enough liquid to swallow them right away.
3. If you have trouble swallowing capsules, open the capsule and sprinkle the contents on a small amount of soft acidic food including applesauce or yogurt. Ask your doctor about other foods you can mix with ULTRESA.
4. If you sprinkle ULTRESA on food, swallow it right after you mix it and drink plenty of water or juice to make sure the medicine is swallowed completely. Do not store ULTRESA that is mixed with food. Throw away any unused portion of capsule contents.

5. If you forget to take ULTRESA, wait until your next meal and take your usual number of capsules. Take your next dose at your usual time. **Do not take two doses at one time.**

What are the possible side effects of ULTRESA?

ULTRESA may cause serious side effects, including:

- See **“What is the most important information I should know about ULTRESA?”**
- **Irritation of the inside of your mouth.** This can happen if ULTRESA is not swallowed completely.
- **Increase in blood uric acid levels.** This may cause worsening of swollen, painful joints (gout) caused by an increase of uric acid levels in your blood.
- **Allergic reactions, including** trouble breathing, skin rash, itching, or swollen lips.

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

The most common side effects of ULTRESA include:

- headache
- throat pain
- nose bleeds

Other possible side effects:

ULTRESA 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 possible side effects of ULTRESA. 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 ULTRESA?

- Store ULTRESA at room temperature between 68°F to 77°F (20°C to 25°C). Avoid heat.
- ULTRESA capsules should be stored in a dry place in the original container.

- After opening the bottle, keep it closed tightly between uses to keep your medicine dry (protect it from moisture).
- The ULTRESA bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). **Do not throw away or eat the desiccant packet.**

Keep ULTRESA and all medicines out of the reach of children.

General information about the safe and effective use of ULTRESA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ULTRESA for a condition for which it was not prescribed. Do not give ULTRESA 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 ULTRESA. If you would like more information, talk to your doctor. You can ask your doctor or pharmacist for information about ULTRESA that is written for health professionals.

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

What are the ingredients in ULTRESA?

Active ingredient: lipase, protease, amylase

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, gelatin, hydrogenated castor oil, hypromellose phthalate, iron oxides, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide triethyl citrate.

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

Marketed by:

Aptalis Pharma US, Inc
22 Inverness Center Parkway
Birmingham, AL 35242 USA

Manufactured by:

Aptalis Pharma S.r.L.
Pessano, Italy 20060

Issued March 2012

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