

MEDICATION GUIDE

ZENPEP® (ZEN-pep) (pancrelipase) delayed-release capsules

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

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

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

What is ZENPEP?

ZENPEP is a prescription medicine for people who cannot digest food normally because their pancreas does not make enough enzymes. ZENPEP may help your body use fats, proteins and sugars from food.

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

ZENPEP is safe and effective in children.

What should I tell my doctor before taking ZENPEP?

Before taking ZENPEP, 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 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 ZENPEP will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed. It is not known if ZENPEP passes into your breast milk. You and your doctor should decide if you will take ZENPEP or breastfeed.

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

- **Take ZENPEP exactly as your doctor tells you.**
- Do not take more capsules in a day than the number your doctor tells you. (total daily dose).
- Always take ZENPEP with a meal or snack. If you eat a lot of meals or snacks in a day, be careful not to go over your total daily dose.
- **Do not crush or chew the ZENPEP capsules or its contents, and do not hold the capsule or contents in your mouth.** Crushing, chewing or holding the ZENPEP Capsules in your mouth may cause irritation in your mouth or change the way ZENPEP works in your body.

Giving ZENPEP to children and adults:

- Swallow ZENPEP capsules whole and take them with enough liquid to swallow them right away.
- If you have trouble swallowing capsules, open the capsules and sprinkle the beads on a small amount of acidic food such as applesauce, pureed bananas or pears. Ask your doctor about other foods you can mix with ZENPEP.
- If you sprinkle ZENPEP on food, swallow it right after you mix it. Do not store ZENPEP that is mixed with food.
- Swallow the ZENPEP and food mixture right away followed with water or juice. Make sure the medicine is swallowed completely.
- If you forget to take ZENPEP, call your doctor or wait until your next meal and take your usual number of capsules. **Do not make up for missed doses.** Take your next dose at the usual time.

Giving ZENPEP to infants (children up to 12 months):

1. Give ZENPEP right before each feeding of formula or breast milk.
2. Do not mix ZENPEP capsule contents directly into formula or breast milk.
3. Open the capsule and sprinkle the contents on a small amount of applesauce, pureed bananas or pears. These foods should be the kind found in baby food jars that you buy at the store, or other food recommended by your doctor. You may also sprinkle the contents directly into your child's mouth.
4. If you sprinkle the ZENPEP on food, give the ZENPEP and food mixture to your child right away.
5. Give your child enough liquid to completely swallow the ZENPEP contents or the ZENPEP and food mixture.
6. Look in your child's mouth to make sure that all of the medicine has been swallowed.

What are possible side effects of ZENPEP?

ZENPEP may cause serious side effects, including:

See “What is the most important information I should know about ZENPEP?”

- 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.

The most common side effects of ZENPEP include

- Pain in your belly
- Gas
- Headache

Other Possible Side Effects

ZENPEP 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 does not go away.

These are not all the possible side effects of ZENPEP. 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 at 1-888-936-7371.

How do I store ZENPEP?

- Store ZENPEP at room temperature (68° to 77°F; 20° to 25°C). Avoid heat.
- After opening the bottle, keep it closed tightly between doses
- DO NOT eat or throw away the packet (desiccant) in your medicine bottle. This packet will protect your medicine from moisture.
- Store ZENPEP in a dry place.

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

General information about ZENPEP

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

This Medication Guide summarizes the most important information about ZENPEP. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about ZENPEP that is written for health professionals. For more information, go to www.ZENPEP.com or call 1-888-ZENPEP1 (1-888-936-7371).

What are the ingredients in ZENPEP?

Active ingredient: lipase, protease, amylase

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hydrogenated castor oil, hypromellose phthalate, magnesium stearate, microcrystalline cellulose, talc, and triethyl citrate in hypromellose capsules.

The red radial imprinting on the 3,000 capsule strength contains, antifoam DC 1510, industrial methylated spirit, iron oxide red C.I. 77491-E172, n-butyl alcohol, shellac and soya lecithin.

The blue radial imprinting on the 5,000, 10,000, 15,000, 20,000, 25,000, and 40,000 capsule strengths contains dehydrated alcohol, FD&C Blue #2 aluminum lake C.I. 73015-E132, isopropyl alcohol, n-butyl alcohol, propylene glycol, shellac and strong ammonia solution.

Capsule shell ingredients:

3,000 USP units and 5,000 USP units of lipase contain carnauba wax or talc,

carrageenan, hypromellose, potassium chloride, titanium oxide, and water.
10,000 USP units of lipase contain carnauba wax or talc, carrageenan, hypromellose, potassium chloride, titanium oxide, water and yellow ferric oxide.
15,000 USP units of lipase contain carnauba wax or talc, carrageenan, hypromellose, potassium chloride, red ferric oxide, titanium oxide, and water.
20,000 USP units of lipase contain carnauba wax or talc, carrageenan, FD&C Blue #2, hypromellose, potassium chloride, titanium oxide, water, and yellow ferric oxide.
25,000 USP units of lipase contain carnauba wax or talc, carrageenan, FD&C Blue #2, hypromellose, potassium chloride, titanium oxide, and water.
40,000 USP units of lipase contain carnauba wax or talc, carrageenan, FD&C Yellow #6, hypromellose, potassium chloride, titanium oxide, and water.

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

Manufactured by:

Aptalis Pharma S.r.l.
Via Martin Luther King, 13
20060, Pessano con Bornago
Milan, Italy

Marketed by:

Aptalis Pharma US, Inc.
100 Somerset Corporate Boulevard
Bridgewater, NJ, 08807
USA

©2014 Aptalis Pharma US, Inc.
Issued March 2014
PKG-XXXX
03/2014 rev. 10