

MEDICATION GUIDE
ZENPEP® (ZEN-pep)
(pancrelipase)
delayed-release capsules, for oral use

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 especially if taken at a high dose for a long time in children with cystic fibrosis. 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 by your doctor. **Do not** take more ZENPEP than directed by your doctor.

What is ZENPEP?

- ZENPEP is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes.
- ZENPEP contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas.
- ZENPEP is safe and effective in adults and children.

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.
- are breastfeeding or plan to breastfeed. It is not known if ZENPEP passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take ZENPEP.

Tell your doctor about all the medicines you take, including prescription and over-the-counter 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 ZENPEP?

- **Take ZENPEP exactly as your doctor tells you.** Contact your doctor if you continue to have signs and symptoms of malabsorption (not absorbing nutrients from food) such as abdominal pain, abdominal distention, bloating, fatty stools, or weight loss. Your dose may need to be changed.
- You should not switch ZENPEP 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 (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.
- **ZENPEP capsules should be swallowed whole. Do not crush or chew the ZENPEP capsules or its contents and do not hold the capsule contents in your mouth.** Crushing or chewing the ZENPEP capsules may cause irritation in your mouth or change the way ZENPEP works in your body.

Giving ZENPEP to Adults and Children 12 Months of Age and Older:

- Swallow ZENPEP capsules whole and take them with enough liquid (water or juice) to swallow them right away.
- If you have trouble swallowing capsules, open the capsules and sprinkle the entire contents on a small amount of acidic soft food such as applesauce, 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 from Birth to 12 Months of Age):

The 2 ways to give ZENPEP to infants (children from birth to 12 months of age), which are described below:

a) Giving with an Acidic Soft Food

1. Before each breastfeeding session or each time you give 120 mL of formula, carefully open the capsule and sprinkle the entire contents of the capsule in a small amount of acidic soft food (such as, store bought preparations of applesauce, bananas or pears)
2. Mix the capsule contents evenly through the food. Be careful not to crush the ZENPEP capsule contents while mixing.
3. Give the entire mixture to the infant right away. **Do not** store the ZENPEP mixture or save for later use.
4. **Do not** mix the ZENPEP capsule contents directly into a bottle of breast milk or formula.
5. Give your infant enough formula or breastfeed your infant **right away** to completely swallow the ZENPEP food mixture.
6. Look into your infant's mouth to make sure that all of the medicine has been swallowed.
7. Throw away the empty ZENPEP capsule.

b) Giving Directly Into the Infant's Mouth Before Breastfeeding or Formula Feeding

1. Before each breastfeeding session or each time you give 120 mL of formula, carefully open the ZENPEP capsule and sprinkle the capsule contents directly into the infant's mouth.
 2. **Do not** mix the ZENPEP capsule contents directly into a bottle of breast milk or formula.
 3. Give your infant additional breast milk or formula **right after** ZENPEP to completely swallow the ZENPEP capsule contents.
 4. Look in your infant's mouth to make sure that all the medicine has been swallowed.
 5. Throw away the empty ZENPEP capsule.
- If a dose is missed, give the next dose with the next feeding.

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?"**
- **Irritation of the inside of your mouth.** This can happen if ZENPEP is not swallowed completely.
- **Increase in blood uric acid levels (hyperuricemia).** This may happen in people with gout, kidney problems, or those who take high doses of pancrelipase, the active ingredient in ZENPEP. Call your doctor if you have pain, stiffness, redness or swelling of your joints.
- **Severe allergic reactions.** Severe allergic reactions have happened in people taking pancreatic enzyme products like ZENPEP. Stop taking ZENPEP and get emergency treatment right away if you have any of these symptoms: trouble with breathing, skin rashes, swollen lips, or itching.

The most common side effects of ZENPEP include:

- Headache
- Bruising
- Cough
- Feeling full after eating a small amount of food

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.

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 Aimmune Therapeutics, Inc at 1-833-AIM2KNO (1-833-246-2566).

How do I store ZENPEP?

- Store ZENPEP at room temperature between 68°F to 77°F (20°C to 25°C). Avoid heat.
- After opening the bottle, keep it closed tightly between uses to protect from moisture.
- Do not eat or throw away the packet (desiccant) in your medicine bottle, if present. Keep it in the 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 the safe and effective use of 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.

You can ask your pharmacist or doctor for information about ZENPEP that is written for health professionals.

What are the ingredients in ZENPEP?

Active ingredients: 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 red iron oxide as colorant.

The blue radial imprinting on the 5,000, 10,000, 15,000, 20,000, 25,000, and 40,000 capsule strengths contains FD&C Blue #2 as colorant.

The black radial imprinting on the 60,000 capsule strength contains black iron oxide as colorant.

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 FD&C Yellow #6, hypromellose, and titanium oxide.
- 60,000 USP units of lipase contain FD&C Blue #1, hypromellose and titanium oxide.

Manufactured by:

Zenpep LLC
1007 US Highway 202/206,
Bridgewater, NJ 08807, USA
Product of Germany
US License No. 2198

Manufactured for:

Aimmune Therapeutics, Inc.
Bridgewater, NJ 08807, USA

For further information, please go to www.ZENPEP.com or call Aimmune Therapeutics, Inc at 1-833-AIM2KNO (1-833-246-2566)

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

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