RECENT MAJOR CHANGES
Patients treated with proton pump inhibitors and warfarin concomitantly may need to be monitored for increases in

Hypersensitivity reactions, including anaphylaxis, anaphylactic shock, angioedema, bronchospasm, diarrhea, Stevens-Johnson syndrome, toxic epidermal necrolysis, and angina.

The safety and effectiveness of ZEGERID in pediatric patients less than 18 years of age have not been established. (8.4)

How should I take ZEGERID?

Swallow ZEGERID whole. Do not chew, mix, or break. The contents of a packet of ZEGERID Powder for Oral Suspension into a small cup of water or juice and stir well before drinking. Do not use other liquids or foods. Do not crush or chew the capsule. Do not open the capsule and sprinkle contents into food.

What is ZEGERID?

ZEGERID is a prescription medicine called a proton pump inhibitor (PPI). ZEGERID reduces the amount of acid in your stomach. ZEGERID is used in adults:

1. For up to 8 weeks for healing stomach ulcers.
2. For up to 8 weeks for healing small intestinal ulcers.
3. For up to 7 days to treat heartburn and other symptoms that happen with gastroesophageal reflux disease (GERD).
4. For up to 3 months for ZEGERID 40 mg capsules.
5. For up to 3 months for ZEGERID 20 mg capsules.

Who should not take ZEGERID?

Do not take ZEGERID if you:

1. are allergic to any of the ingredients in ZEGERID.
2. have had a severe reaction to any medicine in the ZEGERID family.
3. have a deficiency of vitamin B12 that has not been treated or a deficiency of cyanocobalamin. (5.8)
4. have a history of Clostridium difficile infection (CDI) (5.7)
5. have a history of osteoporosis, bone loss, or arthritis.
6. have had a bone fracture.
7. have had a fungal infection of the lungs, stomach, or bowel.
8. are taking certain other medicines that can increase the risk of bone fractures. (5.9)
9. have had surgery to remove the stomach, or have had other surgery to stop stomach acid production.
10. have a bleeding disorder and you have had surgery in the last 4 months.
11. have had a stomach or bowel condition that increases the risk of bleeding.

What should I tell my doctor before I take ZEGERID?

Tell your doctor if you:

1. have had a hereditary or family history of osteoporosis.
2. have had a recent fracture or have a bone that is slow to heal.
3. have a history of bleeding disorders.
4. have had surgery to remove the stomach.
5. have had stomach surgery that slows stomach emptying.
6. have a history of peptic ulcer disease.
7. have had surgery that slows stomach emptying.
8. have had surgery to stop stomach acid production.
9. have had a stomach or bowel condition that increases the risk of bleeding.
10. have had surgery to remove the stomach, or have had other surgery to stop stomach acid production.
11. have a bleeding disorder and you have had surgery in the last 4 months.
12. have had a stomach or bowel condition that increases the risk of bleeding.

Tell your doctor about all the medicines you take. This includes prescription and non-prescription medicines, vitamins, and herbal supplements. Do not take any new medicine unless you talk to your doctor first. ZEGERID may affect how other medicines work, and other medicines may affect how ZEGERID works.Especially tell your doctor if you:

1. have or had a stomach or bowel condition that increases the risk of bleeding.
2. are taking medicine for osteoporosis or bone loss.
3. are taking medicine for high blood pressure or high cholesterol.
4. have a history of Clostridium difficile infection (CDI). (5.7)
5. have a history of osteoporosis, bone loss, or arthritis. (5.9)
6. have a bleeding disorder. (5.9)
7. have had surgery to remove the stomach.
8. have had surgery to stop stomach acid production.
9. have had surgery that slows stomach emptying.
10. have had surgery to stop stomach acid production.
11. have had surgery to remove the stomach, or have had other surgery to stop stomach acid production.
12. have a bleeding disorder and you have had surgery in the last 4 months.
13. have had a stomach or bowel condition that increases the risk of bleeding.

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

The medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take ZEGERID?

Take ZEGERID exactly as prescribed by your doctor.

Do not change your dose or stop taking ZEGERID without talking to your doctor.

Take ZEGERID on an empty stomach at least one hour before a meal. (4)

Empty the contents of a packet of ZEGERID Powder for Oral Suspension into a small cup of water or fruit juice. Do not use other liquids or foods. Stir well and drink immediately. Refill cup with water and drink. (4)

Swallow ZEGERID Capsules whole. Do not take ZEGERID Capsules with water or other liquids. Do not chew, crush, or open the capsules. Do not feed to animals.

SWALLOW ZEGERID WHOLE. DO NOT CRUSH, CHOP, OR OPEN.
What are the possible side effects of ZEGERID?

ZEGERID may cause serious side effects, including:

- See "What is the most important information I should know about ZEGERID?"

- Hypersensitivity Reactions: ZEGERID may have caused serious skin reactions such as rash or hives and may have caused swelling of the lips, tongue, or throat. It may cause problems if you have been on ZEGERID for a long time.

- Low magnesium levels in your body. This problem can be serious. Low magnesium can happen in some people who take a PPI medicine for more than 3 months. If low magnesium happens, it usually is after a year of treatment. You may or may not have symptoms of low magnesium.

Tell your doctor right away if you develop any of these symptoms:

- formation of ulcers in the stomach lining
- vomiting or chest pain
- bloody stools
- blood in the urine
- severe nausea
- constipation
- severe abdominal pain
- cramps
- diarrhea
- fast or irregular heartbeat
- shortness of breath
- sweating
- muscle weakness
- dizziness
- fainting
- abnormal or fast heartbeat
- cramps or muscle aches
- jitters or shaking (tremors)
- nervousness
- gas

Other side effects:

- Serious allergic reactions. Tell your doctor if you get any of the following symptoms with ZEGERID:
  - rash
  - itching
  - stuffy or runny nose
  - hoarseness
  - difficulty breathing

Your doctor may stop ZEGERID if these symptoms happen. Using ZEGERID for a long time may cause problems such as swelling and weight gain.

Tell your doctor if you have any side effects that bothers you or that does not go away.

These are all the possible side effects of ZEGERID. 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.

How should I store ZEGERID?

- Store ZEGERID at room temperature between 15°C to 30°C (59°F to 86°F).
- Keep ZEGERID in a tightly closed container.
- Keep ZEGERID out of reach of children.

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

General information about ZEGERID

Medicines are complex substances. For some purposes other than those listed in a Medication Guide, you may want to ask your doctor or pharmacist for information about ZEGERID that is written for healthcare professionals. For more information, go to www.Salis.com or 1-800-321-4576.

What are the ingredients of ZEGERID?

- Active ingredients: omeprazole and sodium bicarbonate

For instructions on how to use ZEGERID, refer to the instructions provided with your prescription.

For instructions on taking ZEGERID Capsules and ZEGERID Powder for Oral Suspension by mouth, see "How should I take ZEGERID?"