INDICATIONS AND USAGE

11.1 Maintenance of healing of erosive esophagitis

4.7 Take ZEGERID exactly as prescribed by your doctor.

5.12 Concomitant Use of ZEGERID with Methotrexate

5.11 Concomitant Use of ZEGERID with Proton Pump Inhibitors (PPIs)

4.7 To lower the risk of stomach bleeding in critically ill people (40 mg, 1 capsule 4 times daily).

4.7 In the event of severe burns.

4.7 Avoid administration of PPIs for longer than medically indicated. If signs or symptoms of severe gastroesophageal reflux disease (GERD) persist, discontinue the PPI alone in 4 to 12 weeks. Serological testing (e.g., ANA) may be positive and may persist long after the PPI is discontinued.

5.10 Concomitant Use of ZEGERID with St. John’s Wort or Rifampin

5.8 Cyanocobalamin (Vitamin B-12) Deficiency

5.7 Hematological

2.3 Cardiovascular

2.2 Gastrointestinal

2.1 Respiratory

1.1 Clinical Experience

1 ZEGERID is available as a capsule and as a powder for oral suspension in 20 mg and 40 mg omeprazole doses.

Table 1: Recommended Doses of ZEGERID by Indication for Adults 18 Years and Older

<table>
<thead>
<tr>
<th>Indication</th>
<th>ZEGERID Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duodenal Ulcer Disease</td>
<td>1 capsule 4 times daily</td>
</tr>
<tr>
<td>Erosive Esophagitis</td>
<td>40 mg, 1 capsule 4 times daily</td>
</tr>
<tr>
<td>Morbidity of Upper Gastrointestinal Bleeding</td>
<td>40 mg, 1 capsule 4 times daily</td>
</tr>
<tr>
<td>Morbidity of Lower Gastrointestinal Bleeding</td>
<td>40 mg, 1 capsule 4 times daily</td>
</tr>
</tbody>
</table>

DRUG INTERACTIONS

5.2 Omeprazole

5.11 Concomitant Use of ZEGERID with Proton Pump Inhibitors (PPIs)

5.10 Concomitant Use of ZEGERID with St. John’s Wort or Rifampin

5.9 Antiretrovirals

5.8 Cyanocobalamin (Vitamin B-12) Deficiency

5.7 Hematological

5.6 Hepatic Impairment

5.5 Bone Fracture

5.4 Special Senses

5.3 Monitoring Parameters

5.2 Omeprazole

5.11 Concomitant Use of ZEGERID with Proton Pump Inhibitors (PPIs)

5.10 Concomitant Use of ZEGERID with St. John’s Wort or Rifampin

5.9 Antiretrovirals

5.8 Cyanocobalamin (Vitamin B-12) Deficiency

5.7 Hematological

5.6 Hepatic Impairment

5.5 Bone Fracture

5.4 Special Senses

5.3 Monitoring Parameters

Table 4

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiretrovirals</td>
<td>Omeprazole concentrations may be reduced.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>ZEGERID may reduce the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>Omeprazole may reduce the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>ZEGERID may increase the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>Omeprazole may increase the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>ZEGERID may decrease the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>Omeprazole may decrease the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>ZEGERID may increase the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>Omeprazole may increase the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>ZEGERID may decrease the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>Omeprazole may decrease the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>ZEGERID may increase the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>Omeprazole may increase the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>ZEGERID may decrease the systemic availability of antiretrovirals.</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>Omeprazole may decrease the systemic availability of antiretrovirals.</td>
</tr>
</tbody>
</table>
If you are on a low-sodium diet or at risk of developing congestive heart failure (CHF), your doctor should decide if you will take ZEGERID.

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 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 59° to 86°F (15° to 30°C).

• Keep ZEGERID capsules in a tightly closed container.

• Keep ZEGERID in a dry place and out of light.

Keep ZEGERID and all medicines out of reach of children.

General information about ZEGERID

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

This Medication Guide summarizes the most important information about ZEGERID. It does not cover all information about ZEGERID that is written for healthcare professionals.

For more information, go to www.Salis.com or 1-800-321-4976.

What are the possible side effects of ZEGERID?

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

• Vitamin B12 deficiency. ZEGERID reduces the amount of vitamin B12 in your body. Vitamin B12 is needed to absorb vitamin B12 properly. Talk with your doctor about the possibility of vitamin B12 deficiency and you have been on ZEGERID for a long time (more than 3 years).

• Low magnesium levels in your body. This problem can be serious. Low magnesium can happen in some people who take ZEGERID regularly for at least 3 months. If low magnesium levels happen, it is usually after a year or more of treatment. You may or may not have symptoms low magnesium.

Tell your doctor right away if you develop any of these symptoms:
• nausea
• dizziness
• abnormal or fast heartbeat

• Jitteriness or twitching
• weakness
• pain or tingling in the hands or feet
• crampons or muscle cramps
• spasms of the voice box

Your doctor may need to check the level of magnesium in your body before you start taking ZEGERID, or during treatment. If you are taking ZEGERID for a long period of time.

• Renal growths (tumors) in the kidneys. People who take PPI medicines for a long time have an increased risk of developing a certain type of kidney tumors called renal cell carcinoma, even after taking PPI medicines for more than 1 year. The most common side effects with ZEGERID include:

• headache
• abdominal pain
• nausea
• diarrhea
• vomiting
• gas

Other side effects:
• Serious allergic reactions. Tell your doctor if you get any of the following symptoms with ZEGERID:

• difficulty breathing
• swelling
• joint pain
• rash
• fever

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