

## ORAL CAVITY & GASTROINTESTINAL TRACT

### 10. ULCER-HEALING AGENTS

#### 10.3. PROTON-PUMP INHIBITORS

## RISEK

### Presentation

Capsules 10mg: Pack of 14 capsules.

Capsules 20mg: Pack of 7, 14, or 28 capsules.

Capsules 40mg: Pack of 14 capsules.

Sterile lyophilized powder for infusion: Pack of 1 vial.

### Composition

Each capsule contains: Omeprazole 10mg, 20mg, or 40mg

Each vial contains: Lyophilized (freeze-dried) omeprazole sodium equivalent to omeprazole 40mg.

### Indications

- Peptic ulcer: short and long term treatment of active benign gastric and active duodenal ulcers, including peptic ulcers associated with use of non-steroidal anti-inflammatory drugs (NSAID) as well as with *Helicobacter pylori* infection.
- Gastro-oesophageal reflux disease: short and long term treatment of severe erosive esophagitis associated with gastro-oesophageal reflux disease, as well as management of acid-related dyspepsia (symptomatic gastro-oesophageal reflux disease).
- Zollinger-Ellison syndrome: management of pathologic gastric hypersecretion associated with Zollinger-Ellison syndrome (including cases resistant to other treatment).
- Acid aspiration: prophylaxis of acid aspiration during general anaesthesia (through gastric acid reduction).

**Risek** vials are indicated as an alternative to oral therapy in patients who are unsuited to receive the medication orally. It is given on a short-term basis by intravenous infusion (*For reconstitution, refer to the insert leaflet.*)

### Dosage and Administration

#### Capsules

Capsules should be taken immediately before meals, preferably in the morning and swallowed whole with liquid without crushing, breaking, or chewing. For those who have difficulty in swallowing, the capsules can be opened and intact granules within can be sprinkled on a tablespoon or mixed with fruit juice or yoghurt and swallowed immediately without chewing.

- Benign gastric and duodenal ulcers: 20mg once daily for 8 weeks in gastric ulceration or 4 weeks in duodenal ulceration.

*Maintenance dose for prevention of relapse in patients with peptic ulcer:* 10mg once daily, increased to 20mg once daily as needed, has been used.

*Severe or recurrent cases:* 40mg once daily.

*Maintenance dose for recurrent ulcer:* 20mg once daily.

- NSAID-associated duodenal or gastric ulcer and gastroduodenal erosions

20 - 40mg once daily for 4 weeks, depending on whether the NSAID is continued or not. A further 4 weeks could follow, if needed.

*Prophylaxis in patients with a history of NSAID-associated duodenal or gastric ulcers, gastroduodenal lesions, or dyspeptic symptoms who require continued NSAID treatment:* In a clinical study,

10mg once daily has been used successfully for the prevention of relapse in susceptible patients.



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- Peptic ulcer associated with *Helicobacter pylori*
  - *H. pylori* eradication phase: triple therapy regimens of **Risek** 20mg, plus *clarithromycin* 500mg, plus either *amoxicillin* 1000mg or *metronidazole* 400mg; all three medications are to be given twice daily for 1 week.
  - *Ulcer healing phase*: 20 - 40mg once daily; treatment may need to be continued for 4-8 weeks to promote ulcer healing (particularly after ulcer haemorrhage or perforation) - *See further dosage recommendations for benign gastric and duodenal ulcers.*
- Gastro-oesophageal reflux disease
  - 20mg once daily for 4 weeks, followed by a further 4 - 8 weeks if not fully healed.
  - Cases refractory to other treatment*: 40mg once daily for 8 weeks.
  - Long-term management of acid reflux disease in patients with healed reflux oesophagitis*: 10mg daily increasing to 20mg once daily if symptoms return.
  - Children over 2 years with severe ulcerating reflux oesophagitis*: 0.7 - 1.4mg/kg daily for 4-12 weeks; maximum daily dose should not exceed 40mg.
- Acid-related dyspepsia (symptomatic gastro-oesophageal reflux disease)
  - 10 - 20mg once daily for 2 - 4 weeks according to the response.
- Zollinger-Ellison syndrome
  - Initially 60mg once daily; usual range 20 -120mg daily. Doses above 80mg should be given in 2 divided doses.
- Prophylaxis of acid aspiration during general anaesthesia
  - 40mg on the preceding evening then 2 - 6 hours before surgery.

#### Vials

- Gastric acid reduction during general anaesthesia (prophylaxis of acid aspiration):
  - 40mg to be completed 1 hour before surgery.
- Benign gastric ulcer, duodenal ulcer, and gastro-oesophageal reflux:
  - 40mg once daily until oral administration becomes possible.
- Zollinger-Ellison syndrome:
  - 60mg once daily. Higher daily doses may be required and the dose should be adjusted individually. When doses exceed 60mg daily, the dose should be divided and given twice daily.

