

# ARTWORK FOR APPROVAL

Size: 150 mm x 120 mm

Board: \_\_\_\_\_

Grammage: 50g/sm

U/V: Print proof

Others: Code No. 206-160

# Revised Artwork

## New Size:

1st Artwork 29-01-2013

### PRESCRIBING INFORMATION

## OMESEC® Capsules (Omeprazole)

اوميسيك كپسولز

#### COMPOSITION:

Each Capsule contains:  
Omeprazole ...B.P. 20mg  
(as enteric coated pellets)  
Mfg. Specs. Brookes

#### ACTION

OMESEC (Omeprazole) belongs to new class of antisecretory compounds the substituted benzimidazoles, that suppresses gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cells. Because this enzyme system is regarded as the acid (proton) pump within the gastric mucosa, OMESEC (Omeprazole) has been characterized as a "GASTRIC ACID PUMP INHIBITOR" in that it blocks the final step of acid production. This effect is dose related and leads to inhibition of both basal and stimulated acid secretions. OMESEC Capsule once daily provides rapid and effective inhibition of day and night time gastric acid secretion with maximum effect being achieved within 4 days of treatment. As a consequence of reduced acid secretion and intra gastric activity, OMESEC (Omeprazole) dose dependently reduces/normalizes acid exposure of the oesophagus in patients with gastro-oesophageal reflux disease (GERD). No tachyphylaxis has been observed during treatment with Omeprazole.

#### EFFECT ON THE HELICOBACTER PYLORI

Helicobacter pylori is associated with acid peptic disease, including duodenal and gastric ulcer disease, in which about 95% and 70% of patients respectively are infected with this bacterium. OMESEC (Omeprazole) has a bactericidal effect on H. Pylori invitro. Eradication of H. Pylori with Omeprazole and antimicrobial is associated with rapid symptom relief, high rates of healing of any mucosal lesion.

#### PHARMACOKINETICS

OMESEC (Omeprazole) Capsules contain an enteric coated pellets formulation of Omeprazole (because Omeprazole is acid-labile), so that the absorption of Omeprazole begins only after the granules leave the stomach. Absorption is rapid, with peak plasma levels of Omeprazole occurring within 0.5 to 3.5 hours. Plasma half-life is 0.5 to 1 hour. Protein binding is approximately 95%. The majority of the drug (about 77%) is eliminated via the kidneys and the remaining in faeces.

#### INDICATION

OMESEC (Omeprazole) indicated for the treatment of duodenal ulcer, gastric ulcer, reflux esophagitis, symptomatic gastro-oesophageal reflux disease.  
NSAID associated gastric and duodenal ulcers or erosions.  
Helicobacter pylori eradication in peptic ulcer disease.  
Zollinger -Ellison syndrome.

#### DOSAGE AND ADMINISTRATION

##### Duodenal Ulcer & Gastric Ulcer:

**Acute Ulcer:** 20mg daily for 2 to 4 weeks

**Chronic Ulcer:** 40mg daily in divided doses for 4 weeks.

##### Gastro-Esophageal Reflux Disease (GERD) or Reflux Esophagitis:

20mg daily for 4 weeks. In severe cases 20 mg daily for 8 weeks.

##### NSAID associated gastric or duodenal ulcers or erosions:

20mg daily for 3 weeks.

##### Helicobacter Pylori (HP) eradications in peptic ulcer disease:

**TRIPLE therapy regimen:** OMESEC 20 mg, amoxicillin 1gm and clarithromycin 500 mg, all twice a day for one week,  
OR

OMESEC 20mg, clarithromycin 250mg and metronidazole 400mg twice a day for one week.

**Zollinger-Ellison Syndrome**

80 mg daily in divided doses. [2 capsules morning, 2 capsules evening]

**CONTRAINDICATION**

Known hypersensitivity to Omeprazole.

**SIDE-EFFECT**

OMESEC is very well-tolerated and adverse effects have generally been mild and reversible.

**NOTE**

When gastric ulcer is suspected, the possibility of malignancy should be excluded as treatment may alleviate symptoms and may delay diagnosis.

**STORAGE**

Store at temperature 15 to 25 °C away from light and moisture.

**PRESENTATION**

Alu Alu blister pack of 14 Capsules

خوراک اور طریقہ استعمال

ڈیوڈ نیل السریا معدہ کا سر

ایکیوٹ السر 20 ملی گرام روزانہ 2 سے 4 ہفتوں تک

کروٹک السر 40 ملی گرام روزانہ تقسیم شدہ خوراک میں 4 ہفتوں تک

گیسٹرو ایسوفیجیل ریفلکس ڈیزیز

20 ملی گرام روزانہ 4 ہفتوں تک بیماری کی شدت میں 20 ملی گرام روزانہ 8 ہفتوں تک

NSAID کی وجہ سے ہونے والے معدہ کے یا ڈیوڈ نیل السریا ایروٹونس

20 ملی گرام روزانہ 3 ہفتوں تک

پپٹک السر میں Helicobacter Pylori (H.P) کے خاتمے کے لیے

تین دواؤں پر مشتمل علاج

اومیسک 20 ملی گرام، ایبوکسیملین 1 گرام اور کلیرتھیرومائین 500 ملی گرام صبح و شام ایک ہفتہ کے لیے یا

اومیسک 20 ملی گرام، کلیرتھیرومائین 250 ملی گرام اور میٹرونڈیازول 400 ملی گرام صبح و شام ایک ہفتہ کیلئے

زولینگر الیڈون سینڈورم

اومیسک 80 ملی گرام تقسیم شدہ خوراک میں (2 کپسول صبح اور 2 شام کو روزانہ)

اسٹوریج:

15 سے 25 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی اور نمی سے بچا کر رکھیں۔

Manufactured by:

**B** Brookes Pharma (Private) Limited  
58/15, Korangi Industrial Area,  
Karachi, Pakistan.  
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E-mail: marketing@brookespharma.com



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D.M. \_\_\_\_\_

Q.A. \_\_\_\_\_

Q.C. \_\_\_\_\_

M.A. \_\_\_\_\_

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Date: 29-01-2013