

# ESORAL<sup>®</sup> MUPS

●●● Esomeprazole MUPS Tablet

## COMPOSITION

Each Esoral MUPS (Multiple Unit Pellet System) tablet contains Esomeprazole pellets (as Esomeprazole Magnesium USP) equivalent to Esomeprazole 20 mg & Esomeprazole 40 mg.

## MUPS TECHNOLOGY

Compaction of multiparticulates is commonly known as MUPS or Multiple Unit Pellet System. The tablets are prepared by compaction of modified release coated pellets along with cushioning granules. MUPS is the latest technology which combines the power of both tablets and pellet-filled capsules in one single dosage form.

## CLINICAL ADVANTAGES OF ESOMEPRAZOLE MUPS TABLET

• Once daily dosing • Minimizes fluctuation in plasma concentration of drug • Ensures reduction of esophageal residence time • Ensures lesser possibility of dose dumping • Ensures uniform drug release • Ensures greater bioavailability • Ensures lesser chance of localized irritation • Ensures better and more uniform drug absorption

## PHARMACODYNAMIC ADVANTAGES

• Since the number of pellets per unit tablet is much more than a conventional pellet-filled capsule, there is reduced inter- and intra-subject variability in drug absorption and clinical response is facilitated. In addition, the risk of dose dumping and incomplete drug release is minimized.

## DESCRIPTION

Esoral<sup>®</sup> MUPS (both Esoral MUPS 20 mg & 40 mg) is a pink color caplet shaped tablet composed of multiple unit enteric coated pellets of Esomeprazole. Esomeprazole (S-isomer of Omeprazole) is acid labile and therefore is administered orally as enteric coated pellets compressed into tablet. Esomeprazole magnesium (a substituted Benzimidazole), reduces gastric acid secretion through a highly targeted mechanism of action. It is a specific inhibitor of the gastric enzyme H<sup>+</sup>,K<sup>+</sup>-ATPase (the proton pump) which is responsible for acid secretion by the parietal cells of the stomach.

## INDICATIONS

### Adults aged 18 & above

• Erosive esophagitis • Maintenance treatment of patients with reflux esophagitis • Nonerosive Reflux Disease (NERD) (i.e. heartburn and regurgitation) • Healing of NSAID associated gastric ulcers • Reduction of risk of NSAID-associated gastric ulcers • *H. pylori* eradication (triple therapy)

### Adolescents aged 12 & above

• Gastroesophageal Reflux Disease (GERD) • *H. Pylori* eradication

## DOSAGE & ADMINISTRATION

### Adults-

Gastroesophageal Reflux Disease (GERD)	Dose	Frequency
Erosive Esophagitis	40 mg	Once daily for 4 to 8 weeks
Maintenance of Healing of Erosive Esophagitis	20 mg	Once daily
Maintenance Treatment of NERD (On-demand)	20 mg	Once daily
Healing of Gastric Ulcers Associated with NSAID Therapy	20 mg	Once daily for 4 to 8 weeks
Risk-Reduction of Gastric Ulcers Associated with NSAID Therapy	20 mg	Once daily
Zollinger-Ellison Syndrome	40 mg to 80 mg	Twice a day

### Adolescents aged 12 & above

Gastroesophageal Reflux Disease (GERD)	Dose	Frequency
Erosive Esophagitis	40 mg	Once daily for 4 weeks
Maintenance Therapy of Healing of Erosive Esophagitis	20 mg	Once daily
<i>H. Pylori</i> Eradication (Esomeprazole MUPS tablet with Amoxicillin and Clarithromycin)	20 mg	Twice daily for 7 days

Esoral MUPS Tablet is not recommended for children under 12 years of age

## CONTRAINDICATIONS

• Hypersensitivity to Esomeprazole, substituted Benzimidazole or any of the compounds of this medication • When used for eradication of *Helicobacter pylori*, the contraindications for Amoxicillin and Clarithromycin should be followed

## SIDE EFFECTS

• Nausea • Headache • Flatulence • Diarrhea • Constipation • Dizziness • Abdominal pain • Vomiting

## PRECAUTION & WARNING

### General

This medicine should not be taken in presence of severe liver problems and severe kidney problems. Esomeprazole may hide the symptoms of other diseases. If the following happens to you, before taking Esomeprazole or during its consumption, you should report to the doctor straight away: loss of weight or difficulty in swallowing, stomach pain or indigestion, vomiting food or blood, passing black stools.

### Drug Interaction

Possible interaction with Clopidogrel, Atazanavir, Ketoconazole, Itraconazole, Voriconazole, Erlotinib, Citalopram, Imipramine, Clomipramine, Diazepam, Phenytoin, Warfarin and Cilostazol.

## USE IN PREGNANCY & LACTATION

The safety of Esomeprazole in pregnancy has not been established. Esomeprazole should not be administered to pregnant women unless the expected benefits outweigh the potential risks. It has not been investigated whether or not Esomeprazole is excreted in human breast milk. No studies in lactating women have been performed. Therefore, Esomeprazole should not be given to nursing mothers unless its use is considered essential.

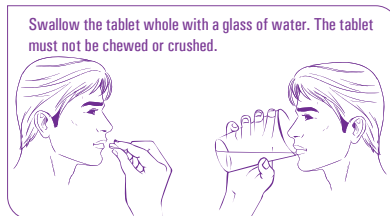
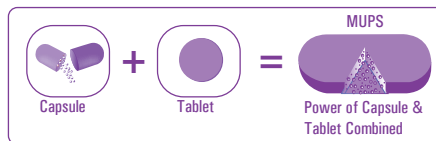
## PHARMACEUTICAL PRECAUTION

Store below 25 °C temperature, away from light and wet place. Keep out of reach of children.

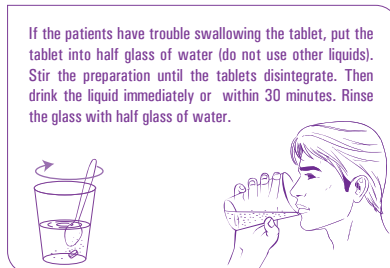
## PACKAGING

Esoral<sup>®</sup> MUPS 20 Tablet: Box containing 5 strips of 10 tablets each. Each tablet contains Esomeprazole 20 mg.

Esoral<sup>®</sup> MUPS 40 Tablet: Box containing 5 strips of 6 tablets each. Each tablet contains Esomeprazole 40 mg.



Or



**SK+F**

Manufactured By  
**ESKAYEF PHARMACEUTICALS LTD.**  
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