

# Imotil<sup>®</sup>

## Loperamide Hydrochloride USP

### COMPOSITION

**Imotil<sup>®</sup>** capsule: Each capsule contains Loperamide Hydrochloride USP 2 mg.

### PHARMACOLOGY

Loperamide (**Imotil<sup>®</sup>**) is orally administered capsule. After administration absorption is more than 65% which occurs at a modest rate, with peak serum levels of 2-3 mg/litre occurring at about 4 hours later after oral administration. The rest 35% is excreted unchanged in the faeces. Loperamide undergoes an extensive presystemic first pass metabolism in the gut wall and in the liver. Loperamide does not act centrally due to its high affinity for the gut wall and its presystemic metabolism. This is why it reaches the systemic circulation in very minute amount. The route of elimination is 0.63-1.4% in urine as unchanged drug, 58% is excreted in the bile and 15-23% appears in the faeces. Loperamide inhibits the peristaltic activity of longitudinal and circular smooth muscle in the intestine by interacting with cholinergic and noncholinergic neuronal mechanisms responsible for producing the peristaltic reflex. Loperamide binds to the opiate receptor in the gut wall, reducing propulsive peristalsis, and increase intestinal transit time.

### INDICATION

**Imotil<sup>®</sup>** is indicated as a symptomatic treatment of acute and chronic diarrhea.

### DOSAGE AND ADMINISTRATION

#### Acute diarrhea:

The initial dose is 2 capsules for adults and 1 capsule for children older than eight; in addition 1 capsule should be taken at any subsequent loose stool.

The daily dose, however should not exceed 8 capsules for adults, for children 4-6 capsules according to age.

#### Chronic diarrhea:

##### Initial dose:

Adults: 2 capsules daily.

Children: Older than eight: 1 capsule daily.

##### Maintenance dose:

One should aim at obtaining normal stools (e.g., one or two stools of good consistency a day). For this it may be necessary to adjust the initial dose (by increasing or decreasing it as required).

Maintenance dose as a rule will vary from 1 to 6 capsules daily.

### CONTRAINDICATION AND PRECAUTION

It should not be used in children less than 4 years of age. It must not be used when inhibition of peristalsis is to be avoided in particular when constipation are present or when abdominal distension develops particularly severely dehydrated children or in patients with acute ulcerative

colitis or pseudomembranous colitis associated with broad spectrum antibiotics. It should not be used alone in acute dysentery associated with blood in stools and elevated temperature. It should be used with caution in patients with defective hepatic function as this might result in a relative overdose.

### SIDE EFFECT

On occasions paralytic ileus, abdominal cramps and bloating have been reported. Other side effects observed are skin reactions including urticaria, nausea, vomiting, constipation, tiredness, drowsiness, dizziness and dry mouth.

### DRUG INTERACTION

No drugs are known to be incompatible with **Imotil<sup>®</sup>**.

### USE IN PREGNANCY AND LACTATION

Safety of use of Loperamide during pregnancy has not been established, although studies in animal did not demonstrate any teratogenic effects. Therefore, it should not be administered to the patients during pregnancy. Although the fraction of loperamide secreted in the human milk is very low, caution is advised if it is to be administered to nursing mothers.

### STORAGE

Store below 30°C. Protect from light & moisture.

Keep out of Children's reach.

### HOW SUPPLIED

**Imotil<sup>®</sup>** capsule: Box containing 200 capsules in blister pack.

Manufactured by



**SQUARE**  
**PHARMACEUTICALS LTD.**

Bangladesh