

## COLODIUM

VICOL12-1 (EXP)

### DESCRIPTION

Green opaque and grey opaque capsule with "HD" printed on one end and "CD 2" on the other end of the capsule.

### COMPOSITION

Loperamide Hydrochloride 2 mg per capsule.

### ACTIONS AND PHARMACOLOGY

Loperamide has an antidiarrhoeal effect. It slows gastrointestinal motility by effects on the circular and longitudinal muscles of the intestine. It binds to opioid receptors in brain homogenates and intestinal strips. Its constipating action is probably due, at least in part, to actions at these receptors. It has an elimination half-life of about 10 hours, metabolised in the liver and excreted predominantly in the faeces.

### INDICATIONS

For the relief of acute nonspecific diarrhoea and of chronic diarrhoea associated with inflammatory bowel disease, as well as to reduce the volume of discharge from ileostomies.

### CONTRAINDICATIONS

Infants and patients with severe colitis or diarrhoea associated with pseudomembranous colitis resulting from treatment with broad spectrum antibiotics.

### PRECAUTIONS

- Loperamide is not recommended for children under 6 years of age. Its use has been associated with fatal episodes of paralytic ileus in infants and young children.
- Appropriate fluid and electrolyte therapy should be given to protect against dehydration in all cases of diarrhoea. Oral rehydration therapy - which is the use of appropriate fluids including oral rehydration salts, remains the most effective treatment for dehydration due to diarrhoea. The intake of as much of these fluids as possible is therefore imperative.
- Drug-induced inhibition of peristalsis may result in fluid retention in the intestine, which may aggravate and mask dehydration and depletion of electrolytes. If severe dehydration or electrolyte imbalance is present, loperamide should be withheld until appropriate corrective therapy has been initiated.
- Safety for use in pregnancy and lactation has not been established.
- Use of this medication should be carefully considered when the following medical problems exist: Conditions where constipation must be avoided, dehydration, diarrhoea caused by infectious organisms, hepatic function impairment.

### MAIN SIDE/ADVERSE EFFECTS

- Abdominal pain and other gastrointestinal disturbances including toxic megacolon.
- Dry mouth.
- Dizziness, fatigue, CNS depression.
- Nausea, vomiting and loss of appetite.
- Skin rashes.
- Constipation.

### OVERDOSAGE

#### Clinical features:

Nausea, epigastric discomfort, constipation, dizziness, drowsiness, stupor and coma.

#### Treatment:

Emesis or gastric lavage is unnecessary unless a very substantial overdose has been ingested.

Naloxone 0.4 to 1.2 mg IV may antagonize the clinical features described above.

### DOSAGE AND ADMINISTRATION

#### Usual adult dose:

Oral, 6 to 8 mg per day up to a maximum of 16 mg per day.

#### Usual paediatric dose:

Below 6 years - Not recommended.  
6 to 8 years - Oral, 4.0 mg per day in divided doses.  
9 to 12 years - Oral, 6.0 mg per day in divided doses.

Note: In general, dietary treatment of diarrhoea in children is preferred whenever possible.

The information given here is limited. For further information, consult your doctor or pharmacist.

#### Storage:

Store below 25°C. Protect from moisture.

#### Presentation/Packing:

Capsule 500's, 10 x 10's.

Marketing Authorization Holder: HOVID Bhd.  
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