

COLODIUM

VICOL13-1 (SIN)

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.
- For sudden (acute) diarrhea, Colodium will usually stop the symptoms within 48 hours. If it does not, stop taking the medicine and see your doctor.**
Do not take this product for anything other than its intended use and never take more than the recommended amount. Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide, the active ingredient in Colodium.

DRUG INTERACTIONS

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines. In particular, tell your doctor or pharmacist if you are taking any of the following:

- ritonavir (used to treat HIV)
- quinidine (used to treat abnormal heart rhythms)
- oral desmopressin (used to treat excessive urination)
- itraconazole or ketoconazole (used to treat fungal infections)
- gemfibrozil (used to lower cholesterol)

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.

If you have taken too much Colodium, immediately contact a doctor or hospital for advice if you have any of the following symptoms: increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating or weak breathing.

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

Adults (including elderly)

- for sudden (acute) diarrhea, take 2 capsules at once, then take 1 capsule after every loose stool. If you have a solid or hard stool, or if you go for 24 hours without a bowel movement, do not take any more capsules.
- for long-lasting (chronic) diarrhea, the right dose should be worked out with your doctor

But: Do not take more than 8 capsules in any 24 hour period!

Usual paediatric dose:

Below 6 years - Not recommended.

Children aged 6 years and over

- for sudden (acute) diarrhea, take 1 capsule to begin with, then 1 capsule after each loose stool. If the child has a solid or hard stool or goes for 24 hours without a bowel movement, do not give any more capsules.
- for long-lasting (chronic) diarrhea, the right dose should be worked out in consultation with your doctor.

But: Never give more than the maximum recommended dose per day and per kilogram of your child's weight!

Child's weight in kilograms (kg)	Maximum number of Colodium capsules per day
from 14 kg	never more than 2
from 20 kg	never more than 3
from 27 kg	never more than 4
from 34 kg	never more than 5
from 40 kg	never more than 6
from 47 kg	never more than 7
from 54 kg	never more than 8

If in doubt, ask your doctor or pharmacist for advice.

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 30°C. Protect from moisture.

Presentation/Packing: Blisters of 10 x 10's.

Product Owner: HOVID Bhd.
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