Radola®

Racecadotril

Description

Radola® is a preparation of Racecadotril which is a prodrug. It is rapidly hydrolyzed to its active metabolite thiorphan which is an enkephalinase inhibitor. Enkephalinase is a cell membrane peptidase located in various tissues, notably in the epithelium of the small intestine. This enzyme hydrolyses or breaks down the exogenous peptides and endogenous peptides such as enkephalins. **Radola**® protects enkephalins from enzymatic degradation thereby prolonging their action at enkephalinergic synapses in the small intestine and reducing water and electrolytes hypersecretion. **Radola**® is a pure intestinal antisecretory active substance. It decreases the intestinal hypersecretion of water and electrolytes induced by cholera toxin or inflammation, and does not have effects on basal secretory activity. **Radola**® exerts rapid antidiarrheal action, without modifying the duration of intestinal transit.

Indication

Radola® is indicated for the symptomatic treatment of acute diarrhea in adults when causal treatment is not possible. If causal treatment is possible, **Radola**® can be administered as a complementary treatment.

Dosage and administration

One capsule initially regardless of the time of day followed by one capsule 3 times daily (preferably before meals). Treatment should be continued until two normal stools are recorded. Treatment should not exceed 7 days. Long term treatment with Racecadotril is not recommended. Dosage adjustment is not necessary for the elderly patients.

Pregnancy and lactation

There are no adequate data from the use of Racecadotril in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy. There is insufficient information on the excretion of Racecadotril in human milk, so Racecadotril should not be administered to pregnant or breastfeeding women.

Hepatic & renal impairment

Caution is advised in patients with hepatic or renal impairment.

Side effects

Common side effects are headache, erythema multiforme, tongue oedema, face oedema, lip oedema, urticaria, tonsillitis, papular rash, prurigo, pruritus, eyelid oedema, angioedema, erythema nodosum and toxic skin eruption.

Contraindications

Racecadotril is contraindicated in patients who have known hypersensitivity to its active substance or to any of the excipients.

Precautions

The administration of Racecadotril does not modify the usual rehydration regimens. The presence of bloody or purulent stools and fever may indicate the presence of invasive bacteria as a reason for diarrhea, or the presence of other severe disease. Therefore, Racecadotril should not be administered under these conditions. Chronic diarrhea has not been sufficiently studied with this medicinal product. Also, Racecadotril has not been tested in antibiotic associated diarrhea.There are limited data in patients with renal or hepatic impairment. So, these patients should be treated with caution.

Drug interactions

No interactions with other active substances have been described in humans to date. In humans, concomitant treatment with Racecadotril and Loperamide or Nifuroxazide does not modify the kinetics of Racecadotril.

Overdose

No cases of overdose have been reported. In adults, single dose above 2 g, which is equivalent to 20 times the therapeutic dose, have been administered, and no harmful effects have been described.

Pharmaceutical precautions

Store in a cool & dry place protected from light. Keep out of the reach of children.

Presentation

Radola® 100 mg capsule: Each capsule contains Racecadotril BP 100 mg.

Package quantities

Radola® 100 mg capsule: Each box contains 40 capsules in blister pack.

ACI Limited
Narayanganj, Bangladesh