Racedot™

Racecadotril BP

COMPOSITION

Racedot™ 100 Capsule: Each capsule contains Racecadotril BP 100 mg.

PHARMACOLOGY

Racecadotril is a prodrug that is hydrolyzed to its active metabolite Thiorphan, which is an inhibitor of Enkephalinase. Enkephalinase is a cell membrane enzyme located in various tissues, notably in the epithelium of the small intestine. This enzyme contributes to the breakdown of an endogenous peptide named Enkephalins. Racecadotril protects Enkephalins from enzymatic degradation thereby prolonging their action at enkephalinergic synapses in the small intestine and reducing hypersecretion.

Racecadotril 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 affect the basal secretory activity. Racecadotril exerts rapid anti-diarrheal action, without modifying the duration of intestinal transit.

Racecadotril is eliminated as active and inactive metabolites mainly via the renal route (81.4%) and to a much lesser extent via the fecal route (around 8%).

INDICATION

Racecadotril is indicated for the symptomatic treatment of acute diarrhea in adults when causal treatment is not possible.

If causal treatment is possible, Racecadotril can be administered as a complementary treatment.

DOSAGE AND ADMINISTRATION

Adults:

One **Racedot**™ 100 capsule initially, then, one capsule three times daily, preferably before the main meals. Treatment should be continued until two normal stools are recorded.

Children:

1.5 mg per kg body weight per administration, three times daily.

Elderly:

Dosage adjustment is not necessary in the elderly.

Caution is advised in patients with hepatic or renal impairment.

Treatment should not exceed 7 days. Long-term treatment with Racecadotril is not recommended.

SIDE EFFECT

Headache, erythema, rash may occur to some patients using Racecadotril. Other most infrequent side effects are erythema multiforme, swelling of tongue, face, lip, eyelid, urticaria, tonsillitis, papular rash, prurigo, pruritus, angioedema, erythema nodosum and toxic skin eruption.

CONTRAINDICATION

Hypersensitivity to Racecadotril or to any of the excipients.

PRECAUTION

The administration of Racecadotril does not modify the usual rehydration regimens. It is essential for the patients to drink abundant liquids. In conditions like the presence of bloody, or purulent stools, fever and in antibiotic-associated diarrhea Racecadotril should not be administered. The product must not be administered to children with renal or liver impairment. Do not administer in cases of prolonged or uncontrolled vomiting due to the possible reduced bioavailability.

USE IN PREGNANCY & LACTATION

Due to a lack of clinical data, Racecadotril should not be administered to pregnant or breastfeeding women.

DRUG INTERACTION

No interactions have been found with other drug substances to date. Joint treatment with Racecadotril and Loperamide, or Nifuroxazide does not modify the kinetics of Racecadotril.

STORAGE

Store at cool and dry place, protected from light and moisture. Keep all medicines out of the reach of the children.

HOW SUPPLIED

Racedot™ 100 Capsule: Box containing 30 capsules in alu- alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Kaliakoir, Bangladesh

TM- Trade Mark

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