Racedo®
(Racecadotril)

Highnoon

COMPOSITION
Racedo 10mg Sachet:
Each sachet contains: Racecadotril 10mg
Racedo 30mg Sachet:
Each sachet contains: Racecadotril 30mg
Racedo 100mg Capsule:
Each capsule contains: Racecadotril 100mg

DESCRIPTION
Racecadotril is an enkephalinase inhibitor that inhibits the breakdown of endogenous opioids, thus reducing secretions.

MECHANISM OF ACTION
Racecadotril is a prodrug, being rapidly hydrolyzed to an active metabolite thiorphan, which is an inhibitor of enkephalinase, a cell membrane peptidase located in various tissues, notably the epithelium of the small intestine. This enzyme contributes both to the hydrolysis of exogenous peptides and to the breakdown of endogenous peptides e.g, enkephalins, Racecadotril is a pure intestinal antisecretory active substance. Racecadotril decreases intestinal hypersecretion of water and electrolytes induced by cholera toxin or inflammation, exerting a rapid antidiarrhoeal action, without modifying the duration of intestinal transit.

PHARMACOKINETICS
Following oral administration, Racecadotril is rapidly absorbed. The initial time to plasma enkephalinase inhibition is 30 min. The bioavailability of Racecadotril is not modified by food, but peak activity is delayed by about 1½ hrs. The biological half-life of enkephalinase was approximately 3 hours. It is bound to plasma proteins, mainly to albumin. The duration of plasma enkephalinase inhibition is about 8 hours.
Racecadotril is rapidly hydrolyzed to thiorphan the active metabolite, which is in turn transformed into inactive metabolites. Repeated administration of Racecadotril does not cause any accumulation in the body. Racecadotril is eliminated as active and inactive metabolites. Elimination is mainly via the renal route and to a much lesser extent via the fecal route.

INDICATIONS
It is indicated for the symptomatic treatment of acute diarrhoea in adults when causal treatment is not possible. If causal treatment is possible, then it can be administered as a complementary treatment.

It is also indicated in infants (over 3 months old) and children as complementary symptomatic treatment of acute diarrhoea together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition, and when causal treatment is not possible.

DOSAGE AND ADMINISTRATION
To initiate therapy in adults, one capsule (containing 100 mg of Racecadotril) is taken regardless of the time of day; after that, one capsule is taken three times daily preferably before meals, until diarrhea stops. Maximum duration of treatment is 7 days.

Treatment should be continued until two normal stools are recorded. Treatment duration should not exceed 7 days. Supportive therapies such as use of oral rehydration salts are encouraged. Racecdo is also available in 10mg and 30mg sachets as granules for oral suspension and is intended for children less than 13kg in weight and in 30mg sachets for children more than that. The recommended dose is determined according to body weight: 1.5mg/kg per dose (corresponding to 1 to 2 sachets), three times daily at regular intervals.
For both adults and children, treatment should be continued until two normal stools are recorded. Treatment should not exceed 7 days and long-term treatment with the drug is not recommended.

Age	Sachets per administration
Children age from 3 months to 9 months (weight less than 9 kg approximately)	1 sachet of 10mg per administration
Children age from 9 months to 30 months (weight from 9 kg to 13 kg approximately)	2 sachets of 10mg per administration
Children age from 30 months to 9 years (weight from 13 kg to 27 kg approximately)	1 sachet of 30mg per administration
Children age over 9 years (weight more than 27 kg approximately)	2 sachets of 30mg per administration
Adults over 18 years	1 capsule of 100mg per administration

Supportive therapies such as use of oral rehydration salts are encouraged.

METHOD OF SACHET ADMINISTRATION
The powder is to be swallowed as it is. It can also be added to food or to a glass of water or feeding bottle, mixing well and followed by immediate administration.

CONTRAINDICATIONS
- Hypersensitivity to Racecadotril or to any of the excipients Lactose, Compressible Sugar (Sucrose & Maltodextrin), Eudragit, Flavor and Colloidal Silicon Dioxide of Racedo.
- Due to the presence of sucrose, it is contraindicated in patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption syndrome or sucrase-isomaltase insufficiency.

WARNINGS AND PRECAUTIONS
- It contains lactose, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Racadotril.
- Functional intestinal disorder (potential exacerbation).
- Caution should be exercised in patients with renal and hepatic impairment.
- Dysentery syndrome with bloody stools / fever (antibiotic therapy required) racecadotril may be ineffective.
- Presence of dehydration (rehydration therapy mandatory).
- Use of racecadotril in antibiotic-associated diarrhea and chronic diarrhea is not recommended.
- Caution should be exercised in diabetic patients and not be administered in cases of prolonged or uncontrolled vomiting.

SPECIAL POPULATION
Use in pregnancy: There are no adequate data from the use of Racecadotril in pregnant women and should not be administered to them.

Use in lactation: Due to the lack of information on secretion of Racecadotril in human milk, it should not be administered to breastfeeding mothers.

Use in children: Racecadotril must not be administered to infants less than 3 months. It must not be administered to children with renal or liver impairment, whatever the degree of severity, due to a lack of information on these patient populations.

ADVERSE REACTIONS
The reported adverse effects are headache, vomiting, dizziness, malaise, fever, respiratory disorders, rash, erythema, erythema multiforme, erythema nodosum, tongue oedema, face oedema, lip oedema, eyelid oedema, angioedema, urticaria, rash papular, prurigo, pruritus, toxic skin eruption, hypokalemia and also tonsillitis in those taking granules.

DRUG INTERACTIONS
No interactions with other drugs have been described in humans to date. In humans, the concomitant treatment with Racecadotril and loperamide or nifuroxide does not modify the kinetics of Racecadotril.
Incompatibilities: Not applicable.

DOSAGE AND INSTRUCTIONS
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION
Racedo 10mg Sachets: Pack of 1 x 16's.
Racedo 30mg Sachets: Pack of 1 x 10's.
Racedo 100mg Capsules: Alu. Alu. Blister pack of 1 x 10's.

ریسیڈو®
(ریسیکاڈوٹرل)

خوراک و ہدایات:
صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

Manufactured by
HIGHNOON LABORATORIES LTD
17.5 KM, Multan Road, Lahore, Pakistan.
www.highnoon-labs.com

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