

165mm

82.5mm

82.5mm

155mm

Raceca

(Racecadotril)

10mg & 30mg Sachet, 100mg Capsule,
175mg Tablet & 4mg/ml oral suspension

رَسِیْکَا
(رَسِیْکَا ڈوٹریل)

۱۰ ملی گرام اور ۳۰ ملی گرام ساخے، ۱۰۰ ملی گرام کپسول،
۱۷۵ ملی گرام ٹیبلٹ اور ۴ ملی گرام / ملی لیٹر اورل سسپنشن

Composition:

Each sachet contains:
Racecadotril..... 10mg

Each sachet contains:
Racecadotril..... 30mg

Each ml contains:
Racecadotril..... 4mg

Each capsule contains:
Racecadotril..... 100mg

Each film coated tablet contains:
Racecadotril..... 175mg

CLINICAL PHARMACOLOGY

Mechanism of Action:

Racecadotril (acetorphan) is an oral enkephalinase inhibitor for use in the treatment of acute diarrhoea. It works by reducing the amount of water and salts released into the intestine during diarrhoea. This helps reduce diarrhoea without slowing down the normal movement of the bowels. It helps control the symptoms of acute diarrhoea and should always be used together with oral rehydration therapy to replace lost fluids and salts.

INDICATIONS:

Racecadotril is used for the symptomatic treatment of acute diarrhoea. It should always be used together with oral rehydration (replacement of fluids and salts) and the usual dietary measures. It does not treat the cause of diarrhoea but helps reduce the symptoms. If the cause of the diarrhoea can be treated, racecadotril may be used in addition to the treatment of the underlying cause.

- **Raceca 4 mg/mL Oral Suspension and Raceca 10 mg and 30 mg Sachets** are used in infants over 3 months of age and children weighing at least 7 kg when oral rehydration and usual supportive measures alone are not sufficient to control acute diarrhoea.
- **Raceca 100 mg Capsules and Raceca 175 mg Tablets** are used in adults for the symptomatic treatment of acute diarrhoea.

Pharmacodynamics:

Racecadotril is a prodrug that is rapidly converted to its active metabolite, thiorphan, an enkephalinase inhibitor. By preventing the breakdown of endogenous enkephalins in the small intestine, it reduces the intestinal hypersecretion of water and electrolytes caused by infection or inflammation. Racecadotril acts as a pure intestinal antisecretory agent and helps reduce the duration and severity of acute diarrhea without affecting normal intestinal transit. It does not cause abdominal distension and has no clinically relevant effects on the central nervous system. At therapeutic doses, racecadotril has not been associated with QT/QTc prolongation

PHARMACOKINETICS

Absorption

Racecadotril is rapidly absorbed after oral administration and is quickly converted to its active metabolite, thiorphan. Peak activity is reached approximately 2 hours after dosing.

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Distribution

Thiorphan is highly bound to plasma proteins, mainly albumin.

Metabolism

Racecadotril is rapidly hydrolyzed to its active metabolite, thiorphan, which is further metabolized into inactive metabolites.

Elimination

The elimination half-life is approximately 3 hours. Racecadotril is eliminated mainly in the urine as metabolites, with a smaller proportion excreted in the faeces. No clinically relevant accumulation has been observed following repeated dosing.

SPECIAL POPULATION

Fertility:

Fertility studies conducted with racecadotril on Rats demonstrate no impact on fertility.

Pregnancy: 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, fertility, embryo-foetal development, childbirth/delivery or postnatal development. However, since no specific clinical studies are available, Raceca should not be administered to pregnant women.

Lactation:

Due to the lack of information regarding racecadotril excretion in human milk, this medicinal product should not be administered to breastfeeding women.

DOSEAGE & ADMINISTRATION

Always take this medicine exactly as your doctor or pharmacist has told you. Racecadotril should be used together with oral rehydration solution and adequate fluid intake.

Racecadotril 4 mg/mL Oral Suspension

For infants over 3 months of age and children weighing 7–52 kg. The recommended dose is 1.5 mg/kg per dose, taken three times daily, preferably before the main meals. Measure the dose using the oral syringe provided.

Racecadotril 10 mg and 30 mg Sachets

For infants over 3 months of age and children weighing 7 kg or more. Mix the granules with a small amount of food or water and give immediately. The recommended dose is 1.5 mg/kg per dose, taken three times daily.

Racecadotril 100 mg Capsules and 175 mg Tablets

For adults. Take one capsule or one tablet three times daily, preferably before the main meals, or as directed by your doctor. Continue treatment until two normal stools are passed. Do not use Racecadotril for more than 7 days unless your doctor advises otherwise. No dose adjustment is required in elderly patients. If you have liver or kidney problems, consult your doctor before taking this medicine.

ROUTE OF ADMINISTRATION

For oral administration only.

ADVERSE REACTIONS

Infections and infestations:

• Uncommon: tonsillitis.

Skin and subcutaneous tissue disorders:

• Uncommon: rash, erythema.
• Unknown: erythema multiforme, tongue oedema, face oedema, lip oedema, eyelid oedema, angioedema, urticaria, erythema nodosum, rash popular, prurigo, pruritus

CONTRAINDICATIONS

• Hypersensitivity to the active substance or to any of the excipients

WARNINGS AND PRECAUTIONS

• Racecadotril should be used together with appropriate oral rehydration therapy (ORT). Intravenous rehydration should be considered in cases of severe or prolonged diarrhea, significant vomiting, or inability to drink fluids.
• If diarrhea is accompanied by blood or pus in the stools, high fever, or persists despite treatment, consult a healthcare professional, as these may indicate a more serious condition.

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- Do not use in infants younger than 3 months due to insufficient clinical data.
- Use with caution in patients with diabetes, as each sachet contains sucrose.
- The use of Racecadotril is not recommended in patients with renal or hepatic impairment because of limited clinical data.
- Prolonged or uncontrolled vomiting may reduce the effectiveness of the medicine.
- Serious allergic reactions, including angioedema (swelling of the face, lips, tongue, throat, or airways), and severe skin reactions have been reported rarely. Discontinue treatment immediately and seek urgent medical attention if these occur.
- Concomitant use with ACE inhibitors may increase the risk of angioedema

EFFECT OF OTHER DRUGS ON RACECADOTRIL

Interaction of racecadotril with ACE inhibitors:

Concomitant use of racecadotril and ACE inhibitors (e.g., captopril, enalapril, lisinopril, perindopril, ramipril) may increase the risk of angioedema. In humans, joint treatment with racecadotril and loperamide or nifuroxazide does not modify the kinetics of racecadotril.

OVERDOSAGE

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

PRESENTATION

Raceca 10 mg & 30 mg sachet are available in packs of 1x10's, 2x10's & 3x10's
Raceca 4mg/ml oral suspension is available in packs of 30ml & 50ml
Raceca 100 mg Capsule is available in packs of 1x10's, 2x10's & 3x10's
Raceca 175 mg tablet is available in packs of 1x10's

Dosage: As directed by the physician.

Instructions:

- Store below 30°C in a dry place, protect from light.
- To be dispensed on the prescription of a registered medical practitioner only.
- Keep out of the reach of children.

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت : دوا کو ۳۰° سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔ بچوں کی پہنچ سے دور رکھیں۔

 **Kaizen**
Pharmaceuticals (Pvt.) Ltd.

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