

ZEDOTT BABY

For the Use of a Registered Medical Practitioner or a Hospital or a Laboratory Only.

Abbreviated Prescribing information for ZEDOTT BABY (Racecadotril 1g Sachet I.P. containing Racecadotril I.P. 10mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Racecadotril is an enkephalinase inhibitor that inhibits the breakdown of endogenous opioids, thus reducing intestinal secretions.

INDICATION: For the treatment of acute diarrhoea in children.

DOSAGE AND ADMINISTRATION: It is intended for infants and children together with ORS. Recommended dose according to body weight is 1.5 mg/kg. For infants: weighing <9 kg-1 sachet 3 times daily, weighing 9-13 kg-2 sachets 3 times daily. Long-term treatment with racecadotril is not recommended. ZEDOTT BABY can be administered directly or mixed with water or beverage. While mixing with water stir well and swallow the total mixture immediately.

CONTRAINDICATION: Racecadotril is contraindicated in patients with known hypersensitivity to the ingredients of the formulation.

WARNINGS & PRECAUTIONS: It is essential to drink abundant liquids with treatment. It may cause prolonged diarrhea, vomiting, lack of appetite. The presence of bloody or purulent stools and fever may indicate the presence of invasive bacteria as a reason for diarrhoea, or the presence of other severe disease. As it has not been tested in antibiotic-associated diarrhea, it should not be administered under this condition. The care should be taken before giving to diabetic patients. It must not be administered to children with renal or liver impairment.

DRUG INTERACTION: No significant drug interactions with antibiotics and oral rehydration salt (ORS).

ADVERSE REACTIONS: Dizziness, malaise, headache, hypokalemia, and vomiting.

MARKETED BY:



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(Additional information is available on request)