For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

ZEDOTT DT

(Racecadotril Dispersible Tablets)

COMPOSITION

ZEDOTT 10 DT

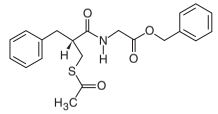
Each uncoated dispersible tablet contains :
Racecadotril I.P. 10 mg
Excipients q.s.

ZEDOTT 30 DT

Each uncoated dispersible tablet contains :
Racecadotril I.P. 30 mg
Excipients q.s.

DESCRIPTION

Racecadotril Benzyl [[(2RS)-2-[(acetylsulfanyl) methyl]-3-phenylpropanoyl]amino]acetate is a lipophilic diesterified prodrug of the enkephalinase inhibitor thiorphan. Its empirical formula is $C_{21}H_{23}NO_4S$ and its molecular weight is 385.5. Its the first and only enkephalinase inhibitor in its class. It is white or almost white powder. It is



practically insoluble in water, freely soluble in methanol and in methylene chloride.

CLINICAL PHARMACOLOGY

Pharmacodynamics:

In peripheral tissues, orally administered racecadotril is rapidly hydrolysed to the more potent enkephalinase inhibitor thiorphan. Within these tissues, membrane-bound enkephalinase enzymes degrade endogenous opioids (enkephalins). Inhibition of enkephalinase by thiorphan increases the availability of opioids, which activate delta ( ) opioids receptors in the gastrointestinal tract. This in turn leads to a reduction in cAMP mucosal levels, resulting in a reduction in the secretion of water and electrolytes into the intestinal lumen (i.e. an antisecretory mechanism in contrast to loperamide which slows gastrointestinal transit).

Pharmacokinetics

After oral administration, racecadotril is rapidly absorbed and quickly metabolized to its active metabolite thiorphan, which in turn mediates all further actions. The activity on plasmatic enkephalinase appears 30 minutes after the administration. The peak plasma concentration of thiorphan is reached 60 minutes after administration of a single oral dose of racecadotril. The biological half-life of enkephalinase activity is 3 hours. The pharmacokinetic parameters of repeated doses of racecadotril are similar on days 1 and 7 as those observed for a single oral dose.

Special Populations

There is no data for use of racecadotril in hepatic or renal insufficiency patients.

INDICATION

For the treatment of acute diarrhoea in children.

CONTRAINDICATIONS

Zedott DT is contraindicated in patients with known hypersensitivity to the ingredients of the formulation.

DRUG INTERACTIONS

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

ADVERSE REACTIONS

Central Nervous System

Dizziness, malaise, and headache have accompanied therapy of acute diarrhoea in a few patients.

Metabolic

Persistence of hypokalemia has been reported infrequently in children with severe watery diarrhoea.

Gastrointestinal

Gastrointestinal adverse effects have been minimal, the incidence often none exceeding that of placebo. Constipation during treatment has been infrequent when placebo effects are eliminated, and less frequent than reported with loperamide. Abdominal distension has not been more common with racecadotril than placebo in available studies. Vomiting has occurred in up to 50% of children treated with racecadotril, although a high incidence has also been seen with placebo. Correcting for placebo effects, the incidence of vomiting in children is low (less than 10%).

OVERDOSAGE

No information is available on overdosage with racecadotril. In case of accidental over dosage, symptomatic treatment should be given.

DOSAGE AND ADMINISTRATION

The recommended dose of racecadotril in children is 1.5mg/kg every eight hourly.

DIRECTION FOR USE:

Disperse the tablets in a teaspoon full of water before administration.

EXPIRY DATE

Do not use after the date of expiry.

STORAGE

Store in a dry place below 25^{o}C. Protect from moisture. Keep out of the reach of children

PRESENTATION

ZEDOTT 10 DT and ZEDOTT 30 DT are available in blister pack of 10 tablets

MARKETED BY

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