

CIPRID®

Brand of Cisapride monohydrate, BP

Prokinetic

DESCRIPTION

CIPRID®, brand of Cisapride, is a gastro-intestinal propulsive motility-enhancing agent (prokinetic).

ACTIONS

CIPRID® enhances and coordinates gastro-intestinal propulsive motility, thereby preventing stasis and reflux. It acts by enhancing the physiological release of acetylcholine at the myenteric plexus. It increases oesophageal peristaltic activity, lowers oesophageal sphincter tone, prevents gastro-oesophageal reflux, increases digestive antroduodenal motility and co-ordination, decreases duodenogastric reflux, improves antroduodenal emptying, enhances intestinal propulsive activity and improves small and large bowel transit. Gastric acid secretion is not affected.

Cisapride is rapidly absorbed from the gastro-intestinal tract. Peak plasma concentrations are achieved 1 to 2 hours after oral administration. It undergoes extensive first-pass metabolism in the liver and gut wall. More than 90% of a dose is excreted as metabolites in the urine and faeces in approximately equal amounts. A small amount is excreted in breast milk. The elimination half-life has been reported to be between 7 and 10 hours. Cisapride is about 98% bound to plasma proteins.

INDICATIONS

- 1-Gastro-oesophageal reflux disorders including curative and maintenance therapy of oesophagitis.
- 2-Gastroparesis: idiopathic or associated with diabetes mellitus, anorexia nervosa, after vagotomy or partial gastrectomy. The symptoms mainly consist of early satiety, anorexia, nausea and vomiting.
- 3-Gastro-intestinal disorders such as early satiety, postprandial fullness, bloating, excessive belching, anorexia, nausea, vomiting, non-ulcer dyspepsia (epigastric burning or pain)
- 4-Intestinal pseudo-obstruction associated with motility dysfunction i e: insufficient propulsive peristalsis; stasis of gastric and intestinal contents.
- 5-Restoration of colonic propulsive motility as a long-term treatment of chronic constipation.
- 6-In babies: chronic and excessive regurgitation or vomiting, when positional and dietary measures have failed.

CONTRAINDICATIONS

Hypersensitivity to cisapride. Strictly contraindicated in patients concomitantly using other oral or parenteral:

- * Antifungals such as Ketoconazole, Itraconazole, Miconazole, Fluconazole.
- * Antibiotics: Erythromycine, Clarithromycine, Troleandomycine.
- * Antidepressant: Nefazodone or some medicines used for the treatment of Aids such as Ritonavir.

PRECAUTIONS

CIPRID® should not be used when stimulation of muscular contractions might adversely affect gastro-intestinal conditions as in gastro-intestinal haemorrhage, obstruction, perforation, or immediately after surgery. It should be used with caution in patients with impaired hepatic function or renal failure. CIPRID® increases intestinal motility and may affect the absorption of other drugs: for example patients on anticoagulants may experience increased prothrombin times; the effects of CNS depressants may also be enhanced. Antimuscarinic agents and possibly opioid analgesics antagonise the gastro-intestinal effects of cisapride and H₂-antagonists may increase the bioavailability of cisapride. Ketoconazole inhibits the metabolism of cisapride, which may lead to QT-interval prolongation and ventricular arrhythmias if given concomitantly.

The drug should not be taken in patients concomitantly taking certain other drugs including antibiotics, antidepressants, antifungals and protease inhibitors as stated under contraindications as it can cause severe cardiac rhythm problems.

ADVERSE REACTIONS

Gastro-intestinal disturbances including abdominal cramps, borborygmi, and diarrhoea may occur. When diarrhoea occurs in babies or infants, the dose should be reduced. Headache, light headedness, dizziness, convulsions, extrapyramidal effects, and tachycardia have also been reported. There have been a few cases of disturbances in liver function among patients receiving cisapride and isolated cases of convulsive seizures and extrapyramidal effects.

DOSAGE AND ADMINISTRATION

* Adults: 15-40mg daily in 2-4 doses:

- severe condition: 10mg 3-4 times
- less severe condition: 5mg 3 times
- maintenance treatment of oesophagitis: 10mg twice or 20mg before sleeping.

* Newborn & children: 0.2mg/Kg/intake, 3-4 times daily.

CIPRID® must be given 15 to 30 minutes before meals. Treatment is usually for 4 weeks in patients with dyspepsia but in patients with motility disorders at least 6 weeks' treatment is recommended, while the usual course in gastro-oesophageal reflux disease is 12 weeks.

How to use the pipette with the oral suspension:

- Holding the lower ring, slide the upper ring up to the mark corresponding to the child's weight in kilograms.
- Empty the pipette into a drink by sliding the upper ring down.

AVAILABILITY

Tablets: Packs of 30 tablets, each containing Cisapride (as monohydrate) 5mg, Excipient q.s. 1 tablet.

Reg. No. Lebanon 261360.

Tablets: Packs of 50 tablets, each containing Cisapride (as monohydrate) 10mg, Excipient q.s. 1 tablet.

Reg. No. Lebanon:261359.

Pediatric Suspension (Alcohol & Sugar free): - Bottles of 100ml containing in each 1ml Cisapride (as monohydrate) 1mg, Excipient q.s. 1ml.

Reg. No. Lebanon:261361.