

# Cidine<sup>®</sup>

(Cinitapride)



## Highnoon

### COMPOSITION

**Cidine 1mg Tablet:** Each tablet contains:

Cinitapride (as Acid Tartrate) 1mg

**Cidine Syrup:** Each 5mL contains:

Cinitapride (as Acid Tartrate) 1mg

### DESCRIPTION

Cinitapride is a prokinetic agent.

### MECHANISM OF ACTION

Cinitapride is an orthopramide with gastrointestinal prokinetic activity, with considerable muscarinic properties. It blocks the presynaptic serotonin receptors and increases its release, resulting in greater serotonergic activity. Though it has discrete antidopaminergic activity, this adds to Cinitapride's therapeutic effect. Cinitapride's efficacy could be due to not only an increase in the pressure of the inferior oesophageal sphincter but also due to its prokinetic effect.

### PHARMACOKINETICS

Maximum plasma levels are reached two hours after the oral administration of Cinitapride. Its elimination half-life is 3 to 5 hours for the first 8 hours, with a residual half-life of over 15 hours with extremely low plasma levels after that time. No accumulation has been observed after the repeated administration of Cinitapride.

### INDICATIONS

It is indicated in the treatment of gastroesophageal reflux disease and gastroparesis.

### DOSAGE AND ADMINISTRATION

In adult, it is given as acid tartrate in oral doses of 1mg tablet three times daily.

In adult, the Cidine syrup is given in oral doses of 5ml three time daily before meal.

Since there is no experience of its use in children and adolescents the administration of Cinitapride is not advisable in this age group.

### CONTRAINDICATIONS

Cinitapride should not be administered to patients with

- known hypersensitivity to Cinitapride or any of other excipient of the product (excipients in Cidine tablets: anhydrous lactose, sodium starch glycolate, cellulose, colloidal silica and magnesium stearate; excipients in Cidine syrup: sorbitol solution, propylene glycol, benzoic acid and orange S-900 (Mandarin) flavour).
- Hemorrhages, obstructions or perforations in whom stimulating gastric motility could be harmful.
- Proven tardive dyskinesia to neuroleptic drugs.

### SPECIAL WARNINGS AND PRECAUTIONS

- Prolonged treatment with Cinitapride can cause tardive dyskinesia in elderly patients.
- Cinitapride can prolong cardiac repolarization in in-vitro studies with much higher concentrations than the plasma concentrations found in clinical practice. However, in-vitro studies in both animals and humans have shown no effect on electrocardiogram particularly on the QT interval.
- Cinitapride should be used with caution in elderly patients because it enhances the action of acetylcholine.
- It should not be used in patients in whom an increase in gastrointestinal motility could be harmful e.g., in patients with gastrointestinal hemorrhage, mechanical obstruction or perforation.
- It should be used with caution in patients with the history of dyskinesia induced neuroleptics.

- Driving vehicles or using dangerous machines should be avoided during treatment with Cinitapride.

### INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

- The prokinetic activity of Cinitapride can alter the absorption of some drugs. The patient must inform the doctor whether he/she is under treatment with other drugs.
- Cinitapride can potentiate the effects of phenothiazine and other anti-dopaminergic drugs on the CNS.
- It can reduce the effect of digoxin by reducing its absorption.
- Anticholinergic drugs and opioid analgesics can reduce the effects of Cinitapride on the digestive tract.
- Its sedative effects increases with co-administration with alcohol, tranquilizers, hypnotic or narcotic drugs. Cinitapride can reduce the effect of digoxin by reducing its absorption.

### PREGNANCY AND LACTATION

Even though no teratogenic effects have been seen, Cinitapride should not be administered in the first three months of pregnancy. Should its use be necessary, the physician must assess the risk/benefit ratio.

### ADVERSE EFFECTS

The reported adverse event of Cinitapride are;

Rash, pruritus, itching, diarrhea, sedation, drowsiness, confusion, gynecomastia and angioedema.

### OVERDOSAGE

Overdose may lead to drowsiness, confusion, disorientation and extrapyramidal effects, which normally disappear when the

treatment is stopped. If the symptoms persist, gastric lavage and symptomatic treatment should be given. For extrapyramidal symptoms anti-Parkinson, anticholinergic or antihistaminic drugs with anticholinergic properties should be given.

### 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

**Cidine 1mg Tablets:** Alu. PVC. Blister Pack of 1 x 10's.

**Cidine Syrup:** Glass Amber Bottle of 120mL.

سیدین  
(سینٹاپرائڈ)

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۔

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