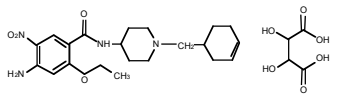
Cinita™
[Cinitapride]

سنیٹا

Tablets 1mg

DESCRIPTION
Cinita (Cinitapride) is a substituted benzamide used for its prokinetic (gastrointestinal motility stimulants with 5-HT receptor antagonist and agonist activity) properties. Chemically, it is N-[1-(3-Cyclohexyl)-methyl] piperidine-4yl] 2-ethoxy-4-amino-5-nitrobenzamide, tartrate. Its molecular formula is $C_{25}H_{36}N_4O_{10}$ and its structural formula is:



Cinitapride hydrogen tartrate

QUANTITATIVE & QUALITATIVE COMPOSITION
Cinita (Cinitapride) Tablets are available for oral administration as:

Cinita Tablets 1mg
Each tablet contains:
Cinitapride hydrogen tartrate
equivalent to cinitapride…1mg

CLINICAL PHARMACOLOGY
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. It also has discrete antidopaminergic activity, this adds to cinitapride's therapeutic effect. Cinitapride efficacy could not only be due to an increase in the pressure of the inferior esophageal sphincter but also due to its prokinetic effect.

Pharmacokinetics
The 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 administrations of Cinitapride.

THERAPEUTIC INDICATIONS
Cinita (Cinitapride) is indicated for the treatment of gastrointestinal disorders associated with motility distrubances such as:
- Gastroesophageal reflux disease.
- Non-ulcer dyspepsia
- Delayed gastric emptying

DOSAGE AND ADMINISTRATION
Adults
The recommended oral dose for the treatment of gastroesophageal reflux disease and functional gastrointestinal motility disorders is one tablet three times daily, 15 minutes before each meal. The dose may be reduce, if required, depending upon the patient's age and symptoms at the discretion of the suggestion.

Children
Not recommended.

CONTRAINDICATIONS
Cinitapride should not be administered to patients with:
- Hemorrhages, obstructions or perforations with stimulating gastric motility could be harmful.
- Proven tardive dyskinesia to neuroleptic drugs.
- Known hypersensitivity to cinitapride or any of the other excipients of the product.

ADVERSE REACTIONS
Common
Drowsiness and diarrhea.

Rare
Extrapyramidal effects (involuntary muscular movements of the head, neck and tongue).

Very Rare
Cutaneous reactions like eruptions, itching or angioedema and gynaecomastia have been reported.

PRECAUTIONS
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 neuro leptics.

Effects on ability to drive and use machines:
During treatment with cinitapride, care should be taken when;
- driving vehicles.
- using dangerous/ heavy machines.

Pregnancy
Cinitapride should not be administered in the first three months of pregnancy. Therefore, cinitapride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

DRUG INTERACTIONS
The prokinetic activity of cinitapride can alter the effects of drugs listed below:
- Cinitapride can potentiate the effects of phenothiazine and other antidopaminergic drugs on the CNS.
- Cinitapride 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.

OVERDOSE
The symptoms of overdose include drowsiness, confusion and extrapyramidal effects. In case of excessive overdosage, the usual measures of gastric lavage and symptomatic therapy should be applied. The extrapyramidal effects should be treated with antiparkinsonians, anticholinergics or antihistaminics with anticholinergic properties.

STORAGE
Store at 25°C (Excursions permitted between 15°C - 30°C). Protect from sunlight and moisture.
The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED
Cinita (Cinitapride) Tablets 1mg are available in blister pack of 10's.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

Manufactured by:

Getz pharma (PVT) LIMITED
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29-30/27, K.I.A., Karachi, Pakistan

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