



MEDLEY PHARMACEUTICALS

CINITOLEY

(Cinitapride hydrogen tartrate)

Tablets 1mg

DESCRIPTION:

CINITOLEY (Cinitapride hydrogen tartrate) is a substituted bezamide used for its Prokinetic (gastrointestinal motility stimulants) properties.

Chemically, Cinitapride is 4-Amino-N-[1-(3-cyclohexen-1-ylmethyl)-4-piperidyl]-2-ethoxy-5-nitrobenzamide. Its molecular formula is $C_{21}H_{30}N_4O_4 \cdot C_4H_6O_6$ and its structural Formula is:

QUANTITATIVE & QUALITATIVE COMPOSITION:

Cinitoley (Cinitapride) Tablets are available for oral administration as:

Cinitoley 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. Though it has discrete anti dopaminergic activity, this adds to cinitapride therapeutic effect. Cinitapride efficacy could be due not only 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:

Cinitoley (Cinitapride) is indicated in the treatment of;

- Gastro esophageal Reflux.
- Functional Gastrointestinal Motility Disorders (slow Gastric emptying).

DOSAGE AND ADMINISTRATION:

Adults

The recommended oral dose for the treatment of Gastro esophageal reflux and functional gastrointestinal Motility disorders (slow gastric emptying) are one tablet three Times daily, 15 minutes before each meal.

Children

Not recommended.

CONTRAINDICATIONS



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ISO 9001-2008 Certified Company
Medley Pharmaceuticals
41-A, P.S.I.E. Jhang Bahtar Road,
Wah Cantt- Rawalpindi



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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.

ADVERSE REACTIONS:

Some patients may notice a slight sedation although cinitapride has not shown sedation while taking the Recommended dose. On rare occasion, there may be extrapyramidal effects with spasm in the muscles of the face, neck and tongue which disappear when the treatment is stopped.

The following may appear on very rare occasions:

- Skin reactions: rash, puritis .
- Gynecomastia.
- Very occasionally angioedema.

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.

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.

HOW SUPPLIED

Cinitoley (Cinitapride) Tablets 1mg :Alu Alu pack of 5×10's packing.

STORAGE

Store below 30°C.

Protect from sunlight and moisture.

The expiration date refers to the product correctly stored in the required conditions.

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.



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