

Package leaflet: information for the user

Cinitrex 1 mg tablets

Cinitapride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cinitrex is and what it is used for
2. What you need to know before you take Cinitrex
3. How to take Cinitrex
4. Possible side effects
5. How to store Cinitrex
6. Contents of the pack and other information

1. What Cinitrex is and what it is used for

Cinitrex belongs to a group of medicines called prokinetics, which are gastrointestinal motility stimulants. Cinitrex is indicated to treat gastroesophageal reflux to enhance the effect of proton-pump inhibitors (medicines reducing gastric acid production) and mild-moderate functional gastrointestinal motility disorders.

2. What you need to know before you take Cinitrex

▪ Do not take Cinitrex

- If you are allergic (hypersensitive) to cinitapride or any of the other ingredients of this medicine (listed in Section 6).
- If you have gastrointestinal bleeding, obstruction or perforation.
- If you have a history of neuroleptic-induced tardive dyskinesia (rapid, repeated movements of the head, neck, trunk or limbs may appear months after treatment has been suspended).

▪ Warnings and precautions

Talk to your doctor or pharmacist before you start taking Cinitrex if you are an elderly patient and you have to take this medicinal product for a prolonged period of time, since it may cause neuroleptic-induced tardive dyskinesia (rapid, repeated movements of the head, neck, trunk or limbs may appear months after treatment has been suspended).

▪ Other medicines and Cinitrex

Tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines.

Cinitrex may increase the neurological effects of some medicinal products, especially of those used to treat nervous system diseases, insomnia and to relieve moderate or intense pain.

Cinitrex may decrease the effect of digoxin, a medicinal product used to treat heart failure.

On the other hand, some medicinal products may decrease the action of Cinitrex. In the case of some medicinal products used to treat Parkinson's disease, abdominal pain or respiratory diseases such as chronic bronchitis.

▪ Cinitrex with food, drink and alcohol

Cinitrex should not be taken with alcohol since it enhances the sedative effects.

▪ Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:

There are no data from the use of cinitapride in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of cinitapride during pregnancy. Your doctor will decide if you should take Cinitrex.

Lactation:

It is unknown whether this medicine is excreted in human milk. As a precautionary measure, it is preferable to avoid the use of cinitapride during lactation.

▪ Driving and using machines

Do not drive nor use dangerous machinery during treatment with Cinitrex.

▪ Cinitrex contains lactose

This medicine contains lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Cinitrex

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Remember to take your medicine.

Use in children and adolescents

Administration of Cinitrex is not recommended in children and adolescents due to a lack of experience with its use in these age groups.

Use in adults (over 20 years old)

Recommended dose for adults (over 20 years old) is 1 tablet, 3 times

a day, 15 minutes before meals.

Increasing recommended doses is neither more effective nor convenient.

Your doctor will tell you the duration of your treatment with Cinitrex. Do not stop the treatment earlier.

Tablets should be taken orally with a glass of water.

If you believe that the action of Cinitrex is too strong or weak, talk to your doctor or pharmacist.

▪ If you take more Cinitrex than you should

If you take more Cinitrex than you should consult your doctor, pharmacist or your local hospital immediately, specifying the medicine and quantity ingested.

Overdose symptoms may be: drowsiness, disorientation and extrapyramidal reactions (involuntary muscle movements of face, neck and tongue) which normally disappear when suspending treatment.

▪ If you forget to take Cinitrex

Do not take a double dose to make up for a forgotten dose. Take the missed dose as soon as you remember and continue on regular schedule. Skip the missed dose if it is almost time for your next scheduled dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Cinitrex can cause side effects, although not everybody gets them. Adverse effects may be:

Uncommon (may affect up to 1 in 100 people)

Some patients may notice a light sedation or somnolence.

Not known (frequency cannot be estimated from the available data)

- Extrapyramidal reactions may occur (involuntary muscle movements of face, neck and tongue).
- Skin reactions may occur, such as rash, itching, angioedema (swelling of lips and tongue that may affect the larynx) gynaecomastia (excessive development of mammary glands), and galactorrhoea (milk secretion).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Cinitrex

Keep this medicine out of the sight and reach of children. Store below 30°C.

Do not use this medicine after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines and packs you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Composition of Cinitrex

The active substance is cinitapride (as hydrogen tartrate). Each tablet contains 1 mg of cinitapride.

The other ingredients (excipients) are: anhydrous lactose, microcrystalline cellulose, sodium starch glycolate (from potato), colloidal silica and magnesium stearate.

What the product looks like and contents of the pack

Cinitrex is presented in tablet form. It comes in yellow, round and biconvex tablets with a break bar on one side. Each pack contains 50 tablets.

Marketing Authorization Holder and Manufacturer

LABORATORIOS NORMON, S.A.
Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

This leaflet was last revised in June 2018