

PACKAGE LEAFLET: INFORMATION FOR THE USER

HIDRASEC

100 mg hard capsules

RACECADOTRIL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Hidrasec is and what it is used for
2. Before you take Hidrasec
3. How to take Hidrasec
4. Possible side effects
5. How to store Hidrasec
6. Further information

1. WHAT HIDRASEC IS AND WHAT IT IS USED FOR

Hidrasec is a medicine used to treat diarrhea.

Hidrasec 100 mg is used to treat symptoms of acute diarrhea in adults.

2. BEFORE YOU TAKE HIDRASEC

Do not take HIDRASEC

If you are allergic (hypersensitive) to racecadotril or any of the other ingredients of Hidrasec (for other ingredients see section "What Hidrasec contains").

Take special care with HIDRASEC

Tell your doctor if:

- If you have blood or pus in your stool, and if you have a high fever. Cause of diarrhea can be a bacterial infection that your doctor should treat,
- If you suffer from chronic diarrhea or diarrhea caused by antibiotics,

- If you have kidney disease or impaired liver function,
- If you suffer from prolonged or uncontrollable vomiting,
- If you have an intolerance to lactose (see section "important information about some of the ingredients of Hidrasec").

Taking other medicines with Hidrasec

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

Use of Hidrasec is not recommended during pregnancy, if you are planning a pregnancy and during breastfeeding.

Consult your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Hidrasec has low impact or no impact on the ability to drive and use machines.

Important information about some of the ingredients of Hidrasec

Hidrasec 100 mg contains lactose (a type of sugar).

If a doctor told you that you have intolerance to some sugars, before you start taking this medicine, consult your doctor.

This product does not contain gluten.

3. HOW TO TAKE HIDRASEC

Hidrasec 100 mg capsules are hard.

Dosage and method of administration

The usual dose is one capsule three times a day, with a glass of water.

Hidrasec should be taken before main meals, but when you first start treatment you can take Hidrasec Capsule at any time of the day.

Dose adjustment is required for elderly patients.

For infants and children, there are other forms of Hidrasec.

Always take Hidrasec exactly as your doctor or pharmacist recommended. You should check with your doctor or pharmacist if you are unsure.

Duration of treatment

A doctor will tell you how long you should take Hidrasec. The treatment should not exceed 7 days.

Dietary measures

To make up for the loss of fluids due to diarrhea, this medicine should be used with the appropriate replacement for fluids and salts (electrolytes). The best compensation for fluid and salt is achieved by the so-called oral rehydration solution (ask your doctor or pharmacist if you are unsure).

If you take more Hidrasec than you should

If you take more Hidrasec than you should, please report it to the pharmacist or doctor.

If you forget to take Hidrasec

Do not take a double dose to replace a forgotten dose. Simply continue the therapy.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hidrasec can cause side effects, although not everybody gets them.

The most common side effects are headache, nausea, and constipation (at least one in 100 patients).

The following uncommon side effects were reported (at least one in 1000 patients): rash and erythema (redness of the skin).

Other side effects of unknown frequency are: Erythema Multiform (pink lesions on the limbs and in the mouth), Glossitis, inflammation of the face, lips, inflammation, inflammation of the eyelids, angioedema (inflammation beneath the skin on different parts of the body), urticaria, erythema nodosum (inflammation in the form of nodes under the skin), papular rash (a rash with smaller lesions, and in the form of nodules), prurigo (skin lesions that itch), itching and generally toxic skin rash.

If you notice any side effects, talk to your doctor or pharmacist.

5. HOW TO STORE HIDRASEC

Keep out of reach and sight of children.

Hidrasec must not be used after the expiry date stated on the blister and carton.

The expiry date refers to the last day of that month.

There are no special conditions for storage.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Hidrasec contains

- the active substance is racecadotril.

One capsule of Hidrasec 100 mg contains 100 mg of racecadotril.

- the other substances are:

Powder: lactose monohydrate

Starch, pregelatinized (corn)

Magnesium stearate

Silicon dioxide, colloidal anhydrous,

Capsule: yellow iron oxide (E172)

Titanium dioxide (E171)

Gelatin

How Hidrasec looks like and contents of the Pack

Hard capsules, Ivory color.

10 hard capsules in blister (PVC/PVDC/Al), in a box.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Abbott International LLC
100 Abbott Park Road,
Abbott Park, Illinois 60064, USA

Manufacturer of the medicinal product

Laboratoires Sophartex
21 rue du Pressoir, F-28500 Vernouillet
France
or
Ferrer Internacional S.A.
94 Gran via Carlos III, Barcelona
Spain