

Package leaflet: Information for the user

Hidrasec 100 mg, hard capsules racecadotril

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

1. What Hidrasec is and what it is used for

Hidrasec is a medicine for the treatment of diarrhoea.

Hidrasec is indicated for the treatment of symptoms of acute diarrhoea in adults, when diarrhoea can not be treated causally.

Racecadotril can be administered as a complementary treatment when causal treatment is possible.

2. What you need to know before you take Hidrasec

Do not take Hidrasec

- * If you are allergic to racecadotril or any of the other ingredients of Hidrasec. (listed in section 6).
- * If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking racecadotril.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hidrasec if :

- * There is blood or pus in your stools and if you have fever. The cause of the diarrhoea may be a bacterial infection that should be treated by your doctor,
- * You are suffering from chronic diarrhoea or diarrhoea caused by antibiotics,
- * You are suffering from kidney disease or impaired liver function,
- * You are suffering from prolonged or uncontrolled vomiting,
- * You have intolerance to lactose (see “Important information about some of the ingredients of Hidrasec”).

Racecadotril, the active substance in Hidrasec, can cause an allergic reaction called angioedema, which can cause swelling of the face, lips, throat or tongue. If you experience these adverse events, stop the treatment immediately and contact your doctor. The swelling may appear at any time during treatment with this product.

Concomitant use of this product and certain other medicines may increase the risk of angioedema (see “Other medicines and Hidrasec”).

Skin reactions have been reported with the use of this product. These are in most cases mild and do not require treatment. In some cases, severe skin reactions may occur. In these cases, the treatment has to be stopped immediately and the patient should not be treated with racecadotril again.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with racecadotril treatment. Stop using racecadotril and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Hidrasec

Please tell your doctor if you are using, have recently used or might use any other medicines. Especially tell your doctor if you use any of the following medicines, as they can increase the risk of certain side effects (see “Warnings and precautions”):

- * ACE inhibitors (e.g. captopril, enalapril, lisinopril, perindopril or ramipril) used to lower the blood pressure or to treat heart failure
- * Angiotensin II antagonists (e.g., candesartan or irbesartan) used to treat high blood pressure and heart failure
- * Sacubitril, used to treat heart failure
- * Some immunosuppressants (e.g. sirolimus or everolimus)
- * Some antidiabetic drugs (e.g. sitagliptin or vildagliptin)
- * Estramustine, used to treat cancer
- * Alteplase, used to treat blood clots

Pregnancy and breast-feeding

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.

Use of Hidrasec is not recommended if you are pregnant, you think you might be or if you are breast-feeding.

Driving and using machines

Hidrasec has little or no effect on the ability to drive and use machinery.

Hidrasec contains lactose.

Hidrasec contains lactose (a type of sugar). If you have been told by your doctor that you have intolerance to some sugars, ask your doctor before taking Hidrasec.

This medicine does not contain gluten.

3. How to take Hidrasec

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

Hidrasec is presented in the form of capsules.

The usual dose is one capsule three times daily to be swallowed with a glass of water.

Hidrasec should be taken preferably before the main meals, but to begin with your treatment, you may take one capsule of Hidrasec at any time during the day.

Your doctor will tell you how long your treatment with Hidrasec will last. It should be continued until two normal stools are produced, not exceeding 7 days.

To compensate for the loss of liquid due to your diarrhoea, this medicinal product should be used together with an adequate replacement of fluid and salts (electrolytes). The best replacement of fluid and salts is achieved with a so-called oral rehydration solution (please ask your doctor or pharmacist if you are not sure). No dosage adjustment is required in the elderly.

Children

Other forms of Hidrasec are available for use in children and infants.

If you take more Hidrasec than you should

If you have taken more Hidrasec than you should have, contact your doctor or pharmacist immediately.

If you forget to take Hidrasec

Do not take a double dose to make up for a forgotten dose. Simply continue with the treatment.

4. Possible side effects

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

You should stop taking Hidrasec and see your doctor immediately if you experience symptoms of angioedema, such as:

- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath

Stop using racecadotril and seek medical attention immediately if you notice any of the following symptoms:

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)
- Breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and a feeling of loss of consciousness which are symptoms of a sudden, severe allergic reaction.

The following side effects have been reported:

Common (may affect up to 1 in 10 people): headache

Uncommon (may affect up to 1 in 100 people): rash and erythema (skin redness).

Not known (*frequency cannot be estimated from the available data*): erythema multiforme (pink lesions in the extremities and inside the mouth), inflammation of the tongue, inflammation of the face, inflammation of the lip, inflammation of the eyelid, urticaria, erythema nodosum (inflammation in the form of a nodule under the skin), rash papular (eruption in the skin with small lesions, hard and nodulated), prurigo (itching skin lesions), pruritus (generalised itching), toxic skin eruption.

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. You can also report side effects directly via

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hidrasec

Keep this medicine out of the sight and reach of children.

Do not use Hidrasec after the expiry date which is stated on the outer packaging after EXP The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Hidrasec contains

- The active substance is racecadotril.
Each capsule contains 100 mg of racecadotril.
- The other ingredients are lactose monohydrate, pregelatinised maize starch, magnesium stearate and colloidal anhydrous silica. The capsule contains gelatin, yellow iron oxide (E 172) and titanium dioxide (E171).

What Hidrasec looks like and contents of the pack

Hidrasec is in the form of ivory-coloured hard capsules.

Each pack contains 6,10, 20, 100 or 500 hard capsules. 100 or 500 pack sizes are for hospital use only
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Bioprojet Europe Ltd.
101 Furry Park road
Killester
EI-DUBLIN 5
IRELAND

Manufacturers

SOPHARTEX
21 rue de Pressoir
28500 Vernouillet
(France)

This medicinal product is authorised in the Member States of the EEA under the following names:

SPAIN:	Tiorfan
AUSTRIA:	Hidrasec
BELGIUM:	Tiorfix
CZECH REPUBLIC:	Hidrasec
DENMARK:	Hidrasec
ESTONIA	Hidrasec
FINLAND:	Hidrasec
GERMANY:	Tiorfan
GREECE:	Hidrasec
HUNGARY:	Hidrasec
IRELAND:	Hidrasec
ITALY:	Tiorfix
LATVIA:	Hidrasec
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LUXEMBURG:	Tiorfix
THE NETHERLANDS:	Hidrasec
POLAND:	Tiorfan
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SWEDEN:	Hidrasec
UNITED KINGDOM:	Hidrasec

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