

Package leaflet: Information for the user

Hidrasec Infants 10 mg, granules for oral suspension 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 your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child 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 used for the treatment of symptoms of acute diarrhoea in children over three months of age. It should be used together with an abundant liquid intake and the usual dietary measures, when these measures are not sufficiently effective on their own to control the diarrhoea, and 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 your child is allergic to racecadotril or any of the other ingredients of Hidrasec. (listed in section 6).
- If you have been told by your doctor that your child has intolerance to some sugars, ask your doctor before you give Hidrasec to your child.
- 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 giving Hidrasec to your child if :

- Your child is under three months of age,
- There is blood or pus in your child stools and if he/she has fever. The cause of the diarrhoea may be abacterial infection that should be treated by your doctor,
- Your child is suffering from chronic diarrhoea or diarrhoea caused by antibiotics,
- Your child is suffering from kidney disease or impaired liver function,
- Your child is suffering from prolonged or uncontrolled vomiting,
- Your child is suffering from diabetes (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 your child experiences 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 child 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 your child is using, has recently used or might use any other medicines.

Especially tell your doctor if your child 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 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 in case of pregnancy and breast feeding.

Driving and using machines

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

Hidrasec contains about 1 g of sucrose per sachet.

If you have been told by your doctor that your child has intolerance to some sugars, ask your doctor before you give Hidrasec to your child.

In infants with diabetes, if the doctor has prescribed to your child more than 5 sachets of Hidrasec per day (which corresponds to more than 5 g of sucrose), this should be taken into account in the child’s total daily intake of sugar.

3. How to take Hidrasec

Always give Hidrasec to your child exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Hidrasec is supplied in the form of granules.

The granules should be added to food or mixed with water in a glass or baby bottle. Mix well and give immediately to your child.

The recommended daily dose depends on your child's weight: 1.5 mg/kg per dose (corresponding to 1 to 2 sachets), three times daily at regular intervals.

In infants weighing up to 9 kg: one sachet per dose.

In infants weighing from 9 to 13 kg: two sachets per dose.

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

To compensate for the loss of liquid due to your child's 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).

If you give more Hidrasec than you should

If your child has taken more Hidrasec than he/she should have, contact your doctor or pharmacist immediately.

If you forget to give Hidrasec:

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

4. Possible side effects

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

You should stop giving Hidrasec to your child and see your doctor immediately if your child experiences 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, light headedness, fast heartbeat, sweating and a feeling of loss of consciousness which are symptoms of a sudden, severe allergic reaction.

The following side effects have also been reported

Uncommon (may affect up to 1 in 100 people):

tonsillitis (inflammation of the amygdales), 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).

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

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 this medicine after the expiry date which is stated on the outer packaging after EXP. The expiry date refers to the last day of that 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 sachet contains 10 mg of racecadotril.
- The other ingredients are : sucrose, colloidal anhydrous silica, polyacrylate dispersion 30 per cent, apricot flavour.

What Hidrasec looks like and contents of the pack

Hidrasec is supplied in the form of granules for oral suspension contained in sachets. Each pack contains 10, 16, 20, 30, 50, or 100 sachets (100 sachets for hospital use).

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
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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
LITHUANIA:	Hidrasec
LUXEMBURG:	TIORFIX
THE NETHERLANDS:	HIDRASEC
POLAND:	Hidrasec-TIORFAN (100mg)
PORTUGAL:	Tiorfan
SLOVAK REPUBLIC:	Hidrasec
SLOVENIA:	Hidrasec
SWEDEN:	Hidrasec
UNITED KINGDOM:	Hidrasec

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