

Package leaflet: Information for the user

HIDRASEC CHILDREN 30 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
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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 cannot 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 use 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.

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 a bacterial 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").

Occurrence of skin reactions has been reported with the use of this product. These are in most cases mild and moderate. When experiencing severe skin reactions, the treatment has to be stopped immediately

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 you use any of the following medicines:

- ACE inhibitor (e.g.captopril, enalapril, lisinopril, perindopril, ramipril) used to lower the blood pressure or facilitate heart labour.

Pregnancy and breast-feeding

Use of Hidrasec is not recommended in case of pregnancy and breast feeding.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

Hidrasec contains sucrose

Hidrasec contains about 3 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 children with diabetes, the quantity of **sucrose** ingested with Hidrasec 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 children weighing from 13 to 27 kg: one sachet per dose.

In children of approximate weight more than 27 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

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 via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

This medicinal product does not require any special storage conditions.

6. Contents of the pack and other information

What Hidrasec contains

The active substance is racecadotril. Each sachet contains 30 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

Manufacturer

SOPHARTEX,
21 rue du 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
LITHUANIA:	Hidrasec
LUXEMBURG:	TIORFIX
THE NETHERLANDS:	HIDRASEC
NORWAY:	Hidrasec
POLAND:	Hidrasec- Tiorfan (100mg)
PORTUGAL:	Tiorfan
SLOVAK REPUBLIC:	Hidrasec
SLOVENIA:	Hidrasec
SWEDEN:	Hidrasec
UNITED KINGDOM:	Hidrasec

This leaflet was last revised in

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