PACKAGE LEAFLET: Information for the user
Hidrasec Infants and Children 4mg/mL 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 questions, please talk to your doctor or pharmacist.
- This medicinal product has been prescribed for your child. Do not give this to anyone else. It may harm them, even if they present the same symptoms as those of your child.
- If your child experiences any side effects, consult your doctor or pharmacist. This also applies to any possible side effects not given in this leaflet. See section 4.

What is in this leaflet?

1. WHAT HIDRASEC INFANTS AND CHILDREN 4MG/ML ORAL SUSPENSION IS AND WHAT IS IT USED FOR?

Hidrasec Infants and Children 4mg/mL is a medicine for the treatment of diarrhoea.

Hidrasec Infants and Children 4mg/mL is used in addition to oral rehydration and dietary measures for the treatment of symptoms of acute diarrhoea in infants and children over 3 months of age and weighing 7 kg and more. It should be used together with the intake of liquids as much as they can drink and the usual dietary measures, when these measures are not sufficient on their own to control the diarrhoea, and when the cause of the diarrhoea can not be treated.
When the cause of the diarrhoea can be treated, racecadotril can be administered in addition to this treatment.

2. WHAT DO YOU NEED TO KNOW BEFORE YOU TAKE HIDRASEC INFANTS AND CHILDREN 4MG/ML ORAL SUSPENSION?

- If your doctor has informed you that your child has an intolerance to certain sugars, please contact your doctor before giving this medicine as it contains sucrose.

Do not give Hidrasec Infants and Children 4mg/mL:

- if your child is allergic to racecadotril or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before giving Hidrasec Infants and Children 4mg/mL to your child if:

- Your child is under three months of age or 7 kg,
- 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 has more than 6 liquid stools per day or has diarrhoea that is accompanied by weight loss,

- 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 section "Hidrasec Infants and Children 4mg/mL contains sodium, sodium benzoate, sucrose and propylene glycol").

Hypersensitivity/Angioneurotic Oedema (swellings) have been reported in patients with racecadotril (the active substance of this product). Angioedema of the face, extremities, lips, mucous membranes, etc., or swelling of the upper airways, e.g. tongue, glottis and/or larynx (throat) may occur. These may appear at any time during therapy. If you experience such adverse events, please stop the treatment immediately and contact your doctor.
Patients with a history of angioedema (swelling) unrelated to racecadotril therapy may be at increased risk of angioedema.

Concomitant use of this medicinal product and other medicines may increase the risk of angioedema (see "Other medicines and Hidrasec Infants and Children 4mg/mL Oral Suspension").

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. Racecadotril should not be reintroduced.

This treatment is administered in addition to oral rehydration and dietary rules. Your doctor will decide if your child needs an oral rehydration solution. You will then have to follow the conditions of use of the oral rehydration solution prescribed by your doctor and follow the advice as regards diet.

Other medicines and Hidrasec Infants and Children 4mg/mL Oral Suspension

Inform your doctor or pharmacist if your child is taking, has recently taken or may take any other medicines, including:

- ACE inhibitor (e.g. perindopril or ramipril) in order to lower blood pressure and ease the work of the heart,
- The angiotensin II antagonists (e.g., candesartan or irbesartan) used to treat high blood pressure and heart failure.

If you give or have recently given another medicine to your child, including over-the-counter medicines, talk to your doctor or pharmacist.

Pregnancy, breastfeeding and fertility

Pregnancy

Ask your doctor or pharmacist before taking any medicine.

Given the available data this medicine is not recommended during pregnancy, whatever the term.

Breastfeeding

In the absence of information regarding transmission of the active substance through breast milk, this medicine should not be used during breastfeeding.

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

Driving and using machines

This medicine has no or a negligible effect on the ability to drive and use machines.

Hidrasec Infants and Children 4mg/mL contains sodium, sodium benzoate, sucrose and propylene glycol

If you have been told by your doctor that your child has an intolerance to some sugars, ask your doctor before you give Hidrasec Infants and Children 4mg/mL to your child.
This medicine contains 225 mg of sucrose per kg-dose. This is to be taken into account for patients with diabetes mellitus.

Patients with fructose intolerance, glucose-galactose malabsorption syndrome or sucrase/isomaltase deficiency (rare hereditary diseases) should not take this medicine.

This medicinal product contains 0.84 mg of sodium (the main component in cooking/table salt) per kg-dose.

The amount of sodium must be included in the maximum nutritional amount recommended by the WHO, corresponding to 1500 mg for children.

This medicinal product contains 1.13 mg of benzoate per kg-dose.

Sodium benzoate may increase the risk of jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks)

This medicinal product contains 1.06 mg of propylene glycol per kg-dose.

3. HOW TO TAKE HIDRASEC INFANTS AND CHILDREN 4MG/ML ORAL SUSPENSION

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

This medicine is an oral suspension with a characteristic strawberry smell.

Only for infants and children between 7 kg and 52 kg.

The recommended dosage is based on child's body weight. It is 1.5 mg/kg/dose (which corresponds to one kg-dose).

On day one: give a first dose immediately to your child and then, depending on the time of the first dose, give up to a maximum of 2 additional doses spread over the day, without exceeding 3 doses over the day. The doses should be preferably administered at the beginning of the three main meals.

On the following days: give 3 doses spread over the day, preferably at the beginning of the three main meals.

The maximum total daily posology is 3 doses.

The medicinal product is administered orally using a syringe (graduated in kg of body weight) providing a 1.5 mg dose of racecadotril per graduation point indicated in kg.

For each dose:

- Infants and children up to 26 kg: use the syringe by filling up to the graduation point indicating the weight of the infant or child.
- Children between 27 and 38 kg (see table below): fill the syringe once up to the 13 kg graduation point and administer the suspension to your child. Fill the syringe a second time until reaching a total that is the same as the child's weight and administer the suspension once again to your child.
- Children between 39 and 52 kg (see table below): fill the 10 mL syringe once up to the 26 kg graduation point and administer the suspension to your child. Fill the 10 mL syringe a second time until reaching a total that is the same as the child's weight and administer the suspension once again to your child.
- For weights exceeding 52 kg, please use the most suitable pharmaceutical forms.

Weight of child	**Graduation for the first filling of the syringe**	**Graduation for the second filling of the syringe**
27 kg	13 kg	14 kg
28 kg	13 kg	15 kg
29 kg	13 kg	16 kg
30 kg	13 kg	17 kg
31 kg	13 kg	18 kg
32 kg	13 kg	19 kg

33 kg	13 kg	20 kg
34 kg	13 kg	21 kg
35 kg	13 kg	22 kg
36 kg	13 kg	23 kg
37 kg	13 kg	24 kg
38 kg	13 kg	25 kg
39 kg	26 kg	13 kg
40 kg	26 kg	14 kg
41 kg	26 kg	15 kg
42 kg	26 kg	16 kg
43 kg	26 kg	17 kg
44 kg	26 kg	18 kg
45 kg	26 kg	19 kg
46 kg	26 kg	20 kg
47 kg	26 kg	21 kg
48 kg	26 kg	22 kg
49 kg	26 kg	23 kg
50 kg	26 kg	24 kg
51 kg	26 kg	25 kg
52 kg	26 kg	26 kg

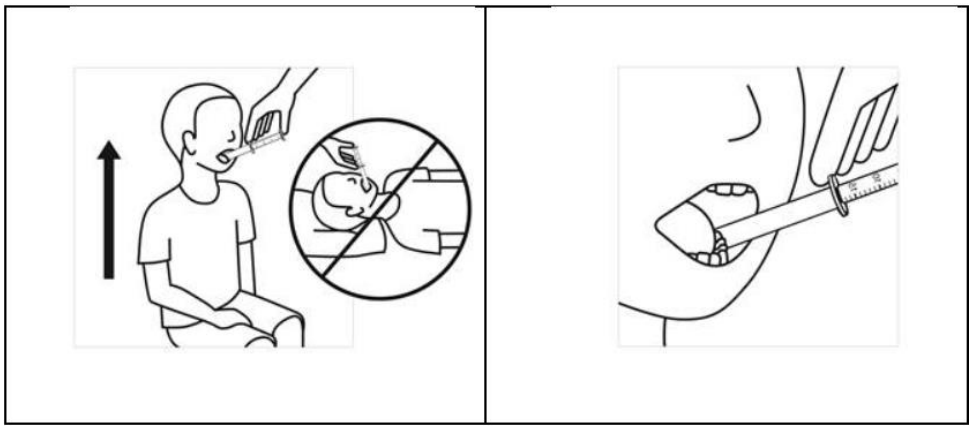
Duration of treatment

Your doctor will tell you how long the treatment with Hidrasec Infants and Children 4mg/mL will last. It should be continued until your child has two normal stools, not exceeding 7 days.

Method of administration

Oral use.

1) Shake vigorously the bottle before use. **Diagram 1**
2) Open the bottle by twisting and pushing down on the child safety cap
3) Fully insert the syringe into the sampling tip. **Diagram 2**
4) To fill the syringe, keep the bottle upside down. Hold the syringe securely in place and pull the plunger slowly and steadily to the required graduation point in kg. **Diagram 3**
5) Place the bottle the right way up once again and remove the syringe. **Diagram 4**
6) Keep the child upright during administration. Insert the syringe into the child's mouth without using force, directing it to the surface of the inner cheek. Administer the entire suspension while gently and gradually pushing down the plunger.



7) After each use, disassemble the oral syringe, rinse with water and dry.

Use of this syringe for oral administration is strictly reserved for the administration of Hidrasec Infants and Children 4mg/mL kg-dose.

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 Infants and Children 4mg/mL, than you should:

Consult your doctor or pharmacist immediately.

If you forget to give Hidrasec Infants and Children 4mg/mL:

Do not give a double dose to make up for the dose that you have forgotten to give your child. Proceed with the next dose.

If you have any questions about using this medicinal product, please talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS?

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

You must stop giving Hidrasec Infants and Children 4mg/mL to your child and consult a doctor immediately if your child experiences symptoms of angioedema such as:

- Swelling of the face, tongue or throat
- Difficulty swallowing
- Hives and difficulties breathing

Uncommon side effects (reported in at least 1 in 1000 patients but fewer than 1 in 100 patients):

Tonsillitis (inflammation of the tonsils), rash (outbreaks on the skin) and erythema (skin redness)

Unknown frequency (cannot be estimated from the available data):

erythema multiforme (pinkish lesions in the extremities and mouth), tongue edema, swelling of the lips, eyelid edema, facial edema, facial angioedema (subcutaneous inflammation affecting various parts of the body), hives, erythema nodosum (inflammation in the form of a lump under the skin), papular rash (rash with small hard and pustular lesions), pruritus (itching affecting the entire body), prurigo (skin lesions causing itching).

Reporting side effects

If your child gets 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 INFANTS AND CHILDREN 4MG/ML ORAL SUSPENSION?

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

Do not give this medicinal product after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

This medicinal product should not be stored at a temperature exceeding 25 °C.

After the first opening, do not use the content of this bottle after 10 days.

Do not use this medicine if you notice any visible signs of deterioration.

On completion of the treatment, return the box, including the syringe for oral administration and the bottle, to your pharmacist so that this medicinal product can be disposed of correctly and appropriately.

Do not throw away any medicines 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 Infants and Children 4mg/mL Oral Suspension contains?

The active substance is racecadotril.

Each mL of oral suspension contains 4 mg of racecadotril.

The other ingredients are:
Sodium benzoate, hydroxyethylcellulose, xanthan gum, sucrose, sodium citrate, lactic acid (for pH adjustment), strawberry flavour (contains propylene glycol). See section 2.

What Hidrasec Infants and Children 4mg/mL Oral Suspension looks like and contents of the pack?

This medicine is an oral suspension with a characteristic strawberry smell.

Packs:

50 mL PET bottle with child safety cap and 10 mL syringe graduated in kg. Box of 1

180 mL PET bottle with child safety cap and 10 mL syringe graduated in kg. Box of 1

Not all presentations may be marketed.

Marketing authorisation holder

BIOPROJET PHARMA
9 RUE RAMEAU
75002 PARIS

Manufacturer

UNITHER LIQUID MANUFACTURING
1-3 ALLEE DE LA NESTE
31770 COLOMIERS

Drug names in the Member States of the European Economic Area

France	Tiorfan
Belgium	Tiorfix
Germany	Tiorfan

Italy	Tiorfan
Luxembourg	Tiorfix
Spain	Tiorfan

The last date on which the leaflet was revised is:

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Other

Detailed information on this medicine is available on the HPRA Website: www.hpra.ie