

HIDRASEC® INFANTS 10MG GRANULES FOR ORAL SUSPENSION

Racecadotril (10mg)

HIDRASEC® CHILDREN 30MG GRANULES FOR ORAL SUSPENSION

Racecadotril (30mg)

What is in this leaflet

1. What Hidrasec® is used for
2. How Hidrasec® works
3. Before you use Hidrasec®
4. How to use Hidrasec®
5. While you are using it
6. Side effects
7. Storage and disposal of Hidrasec®
8. Product description
9. Manufacturer and product registration holder
10. Date of revision

What Hidrasec® is used for

Hidrasec® Infants and Hidrasec® Children is used for the complementary treatment of symptoms of acute diarrhea in infants (older than 3 months) and children. 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 is treated causally.

How Hidrasec® works

Hidrasec® works reducing the amount of fluids secreted into the intestines thus making stools less watery.

Before you use Hidrasec®

- When you must not use it

Do not take Hidrasec® if:

- If you are allergic to racecadotril or any of the ingredients listed at the end of this leaflet
- You have had swelling under the skin with the use of a medicine for high blood

pressure ACE inhibitor (e.g. enalapril, perindopril, etc.)

- You are pregnant or breast feeding

Do not use Hidrasec® if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Hidrasec®.

- Before you start to use it

Take special care with Hidrasec® and tell your doctor if:

- You have problems with your liver or kidneys

If any of the above applies to you, your doctor will tell you whether it is safe for you to start taking Hidrasec®.

- Taking other medicines

It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:

- ACE-inhibitors (e.g. enalapril, perindopril, etc.) used to treat high blood pressure.

How to use Hidrasec®

- How much to use

You should check with your doctor or pharmacist if you are not sure.

Hidrasec® Infants

It is intended for children less than 13kg. The recommended dose is determined according to body weight:

1.5mg/kg per dose (around 1-2 sachets), three times daily at regular intervals. In **infant less than 9kg**, one 10mg sachet 3 times daily. In **infant from 9kg to 13kg**: two 10mg sachets 3 times daily.

Hidrasec® Children

It is intended for children 13kg and above. The recommended dose is determined according to body weight: 1.5mg/kg per dose (around 1-2 sachets), three times daily at regular intervals. In **children from 13kg to 27kg**: one 30mg sachet 3 times daily. In **children of more than 27kg**: two 30mg sachets 3 times daily.

- When to use it

The granules can be added to food, dispersed in a glass of water or in the feeding-bottle, mixing well and followed by immediate administration.

- How long to use it

Treatment should be continued until two normal stools are recorded. Treatment should not exceed 7 days. Please consult your doctor before stopping the treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist

- If you forget to use it

Do not take a double dose to make up for the forgotten dose. Take the next dose at your normal schedule. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

No harmful effects have been reported so far for cases of overdose.

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While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

To avoid dehydration, drink plenty of fluids.

- Things to be careful of

Important information about some of the ingredients of Hidrasec®

Hidrasec® contains sucrose sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Side effects

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

Uncommon side effects (may affect fewer than 1 in 1000 people):

Tonsil inflammation, rash, redness, itchiness, swelling of tongue, face, lip or eyelid

Serious skin reactions (including swelling under the skin) have been reported.

If these reactions occur, Hidrasec® therapy must be discontinued and and consult the doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Hidrasec®

- Storage

Keep this medicine out of the sight and reach of children. Do not use Hidrasec® after the expiry date which is stated on the carton and the sachet after EXP. The expiry date refers to the last day of that month. Do not store above 30°C

- Disposal

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.

Product Description

- What it looks like

Hidrasec® Infant and Hidrasec® Children are white powder with apricot smell.

- Ingredients

- Active ingredient(s)
Racecadotril

- Inactive ingredients

Sucrose, anhydrous colloidal silica, polyacrylate dispersion 30%, apricot aroma.

- MAL number:

Hidrasec® Infants 10mg Granules for Oral Suspension:
MAL13045046AZ
Hidrasec® Children 30mg Granules for Oral Suspension:
MAL13045048AZ

Manufacturer

Sophartex Laboratoires
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France

Product Registration Holder

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Date of revision

- 10/04/2022

Serial Number

NPRA (R1/1) 26042022/104