

Tiorfan Hidrasec Tiorfix Tiorfast 100 mg

PACKAGE LEAFLET

Package leaflet: Information for the user

Tiorfan 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**. Do not pass it on to others. It may harm them, even if their symptoms 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.**

What is in this leaflet

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

1. WHAT TIORFAN IS AND WHAT IT IS USED FOR

Tiorfan is a medicine for the treatment of diarrhoea.

Tiorfan 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 TIORFAN

Do not use Tiorfan

If you are allergic (*hypersensitive*) to racecadotril or any of the other ingredients of Tiorfan (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Tiorfan.

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You should tell your doctor 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 Tiorfan”).

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Other medicines and Tiorfan

Please tell your doctor if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Use of Tiorfan is not recommended if you are pregnant, you think you might be or if you are breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

Important information about some of the ingredients of Tiorfan

Tiorfan 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 Tiorfan.

This medicine does not contain gluten.

3. HOW TO TAKE TIORFAN

Tiorfan is presented in the form of capsules.

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

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

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

Your doctor will tell you how long your treatment with Tiorfan 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 Tiorfan are available for use in children and infants.

If you take more Tiorfan than you should, please contact your doctor or pharmacist immediately.

If you forget to take Tiorfan

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, Tiorfan can cause side effects, although not everybody gets them.

The most common side effects are headache (*affects 1 to 10 users in 100*).

The following uncommon side effects have been reported (*affects 1 to 10 users in 1,000*): rash and erythema (skin redness).

Other side effects (*frequency cannot be estimated from the available data*) are: erythema multiforme (pinklesions in the extremities and inside the mouth), inflammation of the tongue, inflammation of the

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face, inflammation of the lip, inflammation of the eyelid, angioedema (inflammation below the skin in different parts of the body), 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.

You should stop taking Tiorfan 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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE TIORFAN

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

Do not use Tiorfan after the expiry date which is stated on the outer packaging after EXP

The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

This medicinal product does not require any special storage conditions.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tiorfan 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 Tiorfan looks like and contents of the pack

Tiorfan 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 Holders

Bioprojet Europe Ltd.

29 Earlsfort Terrace

EI-Dublin 2

IRELAND

Or

BIOPROJET-FERRER, S.L.

Gran Via Carlos III, 94

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Or

Ferrer Internacional, SA

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08028 Barcelona (Spain)

Manufacturer

FERRER Internacional, S.A.

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Tiorfan Hidrasec Tiorfix Tiorfast 100 mg

or

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:	Tiorfast
CZECH REPUBLIC:	Hidrasec
DENMARK:	Hidrasec
ESTONIA	Hidrasec
FINLAND:	Hidrasec
GERMANY:	Tiorfan
GREECE:	Hidrasec
HUNGARY:	Hidrasec
IRELAND:	Hidrasec
ITALY:	Tiorfix
LATVIA:	Hidrasec
LITHUANIA:	Hidrasec
LUXEMBURG:	Tiorfast
THE NETHERLANDS:	Tiorfan
NORWAY:	Hidrasec
POLAND:	Hidrasec
PORTUGAL:	Tiorfan
SLOVAK REPUBLIC:	Hidrasec
SLOVENIA:	Hidrasec
SWEDEN:	Hidrasec
UNITED KINGDOM:	Hidrasec

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

<[To be completed nationally]>

<Other sources of information>

<Detailed information on this medicine is available on the web site of {MA/Agency}>

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<The following information is intended for healthcare professionals only:>