ERCEFURYL® 200 mg *Nifuroxazide*

Hard capsules

Read all of the leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
 If you have any other questions or doubts, ask your doctor or pharmacist for further information.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What ERCEFURYL 200 mg, hard capsules are and what they are used for
- 2. What you need to know before you take ERCEFURYL 200 mg, hard capsules
- 3. How to take ERCEFURYL 200 mg, hard capsules
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- 1. WHAT ERCEFURYL 200 mg, hard capsules ARE AND WHAT THEY ARE USED FOR

Pharmacotherapeutic group

This medicine is an intestinal antibacterial agent.

Therapeutic indications

It is indicated, as a supplement to rehydration, in the treatment of acute diarrhoea of infectious origin in adults and in children aged over 6 years.

Taking this medicine does not remove the need for dietary measures, and if necessary, rehydration.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE **ERCEFURYL 200 mg, hard capsules**

If your doctor has told you that you are intolerant to some sugars, contact him or her before taking this medicine.

Contraindications Do not use ERCEFURYL 200 mg, hard capsules:

- if you are allergic to nitrofuran derivatives or to any of the other ingredients
- in children under 6 years of age.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Precautions for use and special warnings

Take special care with ERCEFURYL 200 mg, hard capsules:

Special warnings

You should not take this medicine if you have fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare hereditary diseases).

You must see a doctor quickly in the following situations:

- No improvement after 3 days of treatment,
- Onset of fever, vomiting,
- Diarrhea involving more than 6 liquid stools per day or persisting for more than 24 hours or accompanied by weight loss.
- Presence of blood or mucus in the stools,
- Intense thirst, feeling of dry tongue. These signs indicate the start of dehydration, i.e. a significant decrease in liquids due to diarrhea. Your doctor will then decide whether it is necessary to prescribe

rehydration which may be given by oral or intravenous route.

Precautions for use

This treatment is a supplement to the following dietary rules:

- rehydrate with plenty of fluids (sweet or sayoury drinks), in order to compensate for fluid loss due to diarrhéa (average daily water intake: 2 liters);
- maintain food intake throughout the entire episode of diarrhea,
 - excluding certain foodstuffs, especially raw vegetables, fruit, green vegetables, spicy foods, as well as iced drinks or foods.
 - giving preference to grilled meats and rice.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Other medicines and Ercefuryl 200 mg, hard capsules

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Use of Ercefuryl (nifuroxazide) should preferably be avoided during pregnancy.

Breast-feeding is nevertheless possible with short-term nifuroxazide treatment.

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

Driving and using machines

This medicine has no effect on the ability to drive or

Important information about certain ingredients of **ERCEFURYL 200 mg, hard capsules:**

List of excipients with specific effects: sucrose.

3. HOW TO TAKE ERCEFURYL 200 mg, hard capsules **Dosage**

- Adults: 4 capsules a day, to be divided into 2 to 4 intakes
- Children over the age of 6 years: 3 to 4 capsules a day, to be divided into 2 to 4 intakes.

Administration of capsules is contraindicated in children under 6 years of age due the risk of chocking. A more suitable pharmaceutical form is available for younger children.

Method of administration

Oral use.

Swallow the hard capsules with a glass of water.

Duration of treatment

Do not take this medicine for more than 7 days.

If you take more ERCEFURYL 200 mg, hard capsules than you should:

Consult your doctor or pharmacist immediately.

If you forget to take ERCEFURYL 200 mg, hard capsules:

Do not double the dose to make up for the one you missed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ERCEFURYL 200 mg, hard capsules can cause side effects, although not everybody gets them.

 Possible allergic reactions such as rash, hives, angioedema (sudden allergic swelling of a part of the body, most often the face, tongue or neck), or anaphylactic reaction (possibly generalised allergic shock).

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

5. HOW TO STORE ERCEFURYL 200 mg, hard capsules

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

Do not use ERCEFURYL 200 mg, hard capsules after the expiry date printed on the box.

Store at a temperature not exceeding 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist what to do with unused medicines. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER information

What ERCEFURYL 200 mg, hard capsules contain

The active substance is:

Nifuroxazide......200 mg

For one hard capsule. The other ingredients are:

Sucrose, maize starch, magnesium stearate.

Capsule shell: titanium dioxide (E171), yellow iron oxide (E172), gelatin.

What ERCEFURYL 200 mg, hard capsules look like and contents of the pack

This medicine is a hard capsule. Box of 14 and 28.

Marketing Authorization Holder and Operating Company sanofi-aventis France

1-13, boulevard Romain Rolland 75014 Paris

Manufacturer

France

Sanofi Winthrop Industrie 6 Boulevard de l'Europe 21800 Quetigny France

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HEALTH INFORMATION AND ADVICE

WHAT YOU SHOULD KNOW ABOUT ANTIBIOTICS

Antibiotics are effective in fighting infections caused by bacteria. They are not effective against those caused by viruses.

Your doctor has therefore chosen to prescribe this antibiotic for you because it is suitable for you and for the disease you have.

Bacteria are able to survive or to reproduce despite the effect of an antibiotic. This is known as resistance and makes some antibiotic treatments ineffective.

Inappropriate or excessive use of antibiotics increases resistance.

You may promote the growth of resistant bacteria and thus slow down your recovery, or even make this medicine ineffective, if you do not comply with the following:

- prescribed dose.
- administration times,
- duration of treatment.

Therefore, to maintain the efficacy of this medicinal product:

- 1- Only use an antibiotic when your doctor has
- prescribed it for you. 2- Comply strictly with your prescription.
- 3- Do not reuse an antibiotic without a medical prescription even if you think you are fighting an apparently similar disease.
- 4- Never give your antibiotic to someone else it may not be appropriate for their disease.
- 5- Once your treatment is completed, bring all opened boxes to your pharmacist for proper disposal of this medicine.