

PACKAGE LEAFLET: INFORMATION FOR THE USER

ENTEROFURYL

100 mg Capsules, hard

NIFUROXAZIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 only • Do not pass it on to others • It may harm them, even if their signs of illness 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 ENTEROFURYL is and what it is used for
2. Before you take ENTEROFURYL
3. How to take use ENTEROFURYL
4. Possible side effects
5. How to store ENTEROFURYL
6. Further information

1. WHAT ENTEROFURYL IS AND WHAT IT IS USED FOR

ENTEROFURYL is (intestinal anti-infective). ENTEROFURYL capsules are used in adults and children older than 6 years as an adjunct to rehydration in the treatment of acute diarrhea of infectious origin. The treatment does not obviate the need for dietary measures and rehydration when it is required.

2. BEFORE YOU TAKE ENTEROFURYL

Do not take ENTEROFURYL

- If you are allergic to Nifuroxazide, or any of the other ingredients of this medicine (see section 6)
- If it is meant for the treatment of children under 6 years of age

Take special care with ENTEROFURYL

Consult your doctor as a matter of urgency if:

- your condition has not improved after 3 days of use;

- you experience fever or vomiting;
- you produce more than 6 loose stools a day, or your diarrhea persists for more than 24 hours or causes weight loss;
- your stools contain blood or mucus;
- while experiencing heavy thirst, your tongue feels dry.

The above signs indicate dehydration (loss of body liquid) due to diarrhea. In such a case, your doctor may deem fit to prescribe rehydration treatment, which may take the form of orally-administered treatment or an intravenous drip.

This medicine is intended to supplement appropriate dietary changes:

- Keep yourself hydrated with plenty of liquids (with salt or sugar) to compensate for water lost due to diarrhea. Adults require 2 liters of water a day.
- As for what to eat:
- Avoid certain foods – particularly green and raw vegetables, fruit and spicy foods – as well as iced drinks. • – Instead, eat more grilled meat and rice.

Taking other medicines

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

ENTEROFURYL capsules should not be taken with a medicine which may cause disulfiram reaction or CNS depressants.

Taking ENTEROFURYL together with food and drink

Follow the instructions for taking food for the duration of diarrhea (see Cautions).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- You are advised NOT to use this medicine during pregnancy.
- This medicine may be used briefly if you are breast-feeding.

Driving and using machines

The medicine does not influence the ability to drive and use machines.

Important information about some ingredients of ENTEROFURYL

ENTEROFURYL contains saccharose. If your doctor told you have an intolerance to some sugars, contact your doctor before taking this medicine.

ENTEROFURYL may contain colors azorubine (E122) and ponceau 4R (E124) which may cause allergic-type reactions.

3. HOW TO TAKE ENTEROFURYL

Always take ENTEROFURYL exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

- ENTEROFURYL should be used orally (through the mouth). Swallow whole with water.

Dosage

The medicine is used in adults and children older than 6 years.

Adults

Two capsules 4 times a day (800 mg per day).

Children older than 6 years

Two capsules 3-4 times a day (600 mg to 800 mg per day).

The use of capsules is contraindicated in children younger than 6 years, it can lead to strangulation. The use of the suspension is recommended in children.

Duration of treatment

The duration of treatment is limited to 7 days.

If you take more ENTEROFURYL than you should

No symptoms of overdose or poisoning are known for ENTEROFURYL.

If you forget to take ENTEROFURYL

If you take too few ENTEROFURYL capsules or forget to take a dose, do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

The possibility of allergic reactions such as cutaneous eruptions, urticaria, Quincke's edema (sudden swelling of a body part which usually occurs on the face, tongue or neck) or anaphylactic shock (allergic shock, which could be generalized).

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ENTEROFURYL

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container. The expiry date is the last day of the month indicated.

Expiration date:

60 months

Storage conditions:

Do not store above 25 °C.

6. FURTHER INFORMATION**What ENTEROFURYL contains**

One Enterofuryl 100 mg hard capsule contains: nifuroxazide 100 mg.

The medicine Enterofuryl 100 mg hard capsules contain the following excipients: corn starch, sucrose, cellulose powder, magnesium stearate, hard gelatin capsule.

What ENTEROFURYL looks like and contents of the pack

Enterofuryl 100 mg capsules are oblong, hard gelatin capsules with a body and cap. Capsules are yellow.

Enterofuryl 100 mg capsules are packaged in boxes with 30 capsules.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosna i Hercegovina

Manufacturer of medicinal product

Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosna i Hercegovina

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