

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### ENTEROFURYL

200 mg/5 mL oral suspension

### NIFUROXAZIDE

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*• 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 •*

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#### What is in this leaflet?

1. What ENTEROFURYL is and what it is used for
2. Before you take ENTEROFURYL
3. How to take ENTEROFURYL
4. Possible side effects
5. How to store ENTEROFURYL
6. Further information

#### *1. WHAT ENTEROFURYL IS AND WHAT IT IS USED FOR*

This medicine is intestinal anti-infective.

ENTEROFURYL 200 mg/5 mL oral suspension is applied in children older than 2 years and adults in treatment of acute diarrhea of infective origin.

Treatment does not exempt dietary measures and rehydration if they are considered necessary.

#### *2. BEFORE YOU TAKE ENTEROFURYL*

Warn the doctor if you are taking other medicines, you have a chronic disease, a metabolic disorder, hypersensitive to medication or have had an allergic reaction to some of them.

#### **Do not use ENTEROFURYL 200 mg/5 mL oral suspension**

- If you are allergic (hypersensitive) to nitrofurans derivatives or other ingredients of the medicinal product (listed in section 6);
- In premature infants, newborns (0-1 months) and infants younger than 2 years.

Be careful with ENTEROFURYL 200 mg/5 mL oral suspension

### **Special warnings**

If your doctor told you that you have a disease called intolerance to some sugars, before you start using this medicine, consult your doctor.

### **Urgent, consult with your doctor, in the following cases:**

- in case that your condition does not improve after 3 days of treatment;
- in case of high temperature, vomiting;
- in case of blood or mucus in the stool;
- in case of intense thirst, or feelings of dry tongue. Namely, these signs indicate the beginning of dehydration, i.e. significant loss of fluids due to diarrhea. Your doctor will decide whether to prescribe rehydration, which will be performed by oral or intravenous route.

### **Precautions**

Be sure to follow the routes of administration as well as ways of dissolving solution for oral rehydration which your doctor may prescribe, and follow the advice regarding the diet.

This treatment is a supplement to dietary rules:

About the rehydration with large amount of salted or sweet drinks to compensate for the loss of fluids due to diarrhea (average daily water intake in adults is 2 liters)

the food intake for the duration of diarrhea

- avoiding certain foods, especially raw food such as fruits, vegetables, spicy foods, and frozen food or drink;
- preference is given to grilled meat and rice.

You should consult a doctor about the avoidance of milk and dairy products.

### **Taking other medicines**

Keep in mind that this information can apply to medicines that you no longer use, as well as to the medication that you are planning to take in the future. Tell your doctor if you are taking, or have recently taken any other medicine, including the medicine purchased without a prescription.

Concomitant use of Enterofuryl 200 mg / 5 ml oral suspension with medicines that can cause disulfiram reaction or CNS depressants is not recommended.

### **Pregnancy and breastfeeding**

Before you begin to use any medicine, consult your doctor or pharmacist.

This medicine should not be used in pregnancy.

Breast-feeding is possible in the case of short-term treatment with this medicine.

### **Driving and using machines**

The medicine has no effect on the psychophysical abilities of the patient.

### **Other warnings**

This medicine contains sucrose. Its use is not recommended in patients with intolerance to sucrose (a rare hereditary disease).

It contains methyl parahydroxybenzoate (E218) that can cause allergic reactions (or delayed hypersensitivity reactions).

Due to the presence of alcohol in the product, inform your doctor if you are suffering from liver diseases, epilepsy, or if you are pregnant.

## **3. HOW TO TAKE ENTEROFURYL**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Method of administration**

ENTEROFURYL 200 mg/5 mL oral suspension is intended for oral administration.

**Dosing**

The medicine is used in children older than 2 years of age and adults.

**Children older than 2 years:**

3 times a day- 5 mL.

**Adults:** 4 times a day - 5 mL.

**The duration of treatment**

The duration of treatment is limited to 7 days.

**If you take more ENTEROFURYL 200 mg/5 mL oral suspension than you should**

If you take more than the prescribed amount of medicine, immediately contact your doctor or pharmacist!  
There are no described cases of poisoning by this medicine.

**If you forget to take ENTEROFURYL 200 mg/5 mL oral suspension**

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

**If you stop taking ENTEROFURYL 200 mg/5 mL oral suspension**

Take this medicine for as long as your doctor has prescribed.

In case of sudden cessation of taking this medicine, negative effects are not expected. In any case, we recommend that you follow the treatment regimen, if necessary, consult your doctor.

If you have any further questions on the use of ENTEROFURYL 200 mg/5 mL oral suspension, contact your doctor, or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines and ENTEROFURYL 200 mg/5 mL oral suspension may cause side effects.

The possible allergic reactions are Kootenai eruptions, urticaria, Quincke's edema (sudden swelling of the body that is most common on the face, tongue, or throat), or anaphylactic shock (allergic shock which could be generalized).

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.

**5. HOW TO STORE ENTEROFURYL**

Must keep out of reach and sight of children.

Keep at temperature below 30 ° C. Do not freeze.

Used within 14 days after first opening of the vial.

Shelf life: 3 years.

ENTEROFURYL 200 mg/5 mL oral suspension should not be used after the expiry date stated on the carton.

**6. FURTHER INFORMATION****What ENTEROFURYL 200 mg/5 mL oral suspension contains**

5 mL oral suspension contains: nifuroxazide 200.00 mg.

The other ingredients are: sucrose, ethanol 96%, carbomer, banana flavor, methyl parahydroxybenzoate, sodium hydroxide, citric acid anhydrous, purified water. What ENTEROFURYL 200 mg/5 mL oral suspension looks like and contents of the pack.

ENTEROFURYL 200 mg/5 mL oral suspension is a thick suspension, yellow in color, banana flavored.

ENTEROFURYL 200 mg/5 mL oral suspension is packed in a box with a glass bottle with 90 mL of suspension and a plastic teaspoon of 2.5 mL/5 mL.

***Regime of dispensing***

The medicine is issued on doctor's prescription

***Manufacturer***

Bosnalijek d.d.

Jukićeva 53, Sarajevo, Bosnia and Herzegovina

***Manufacturer of the medicinal product***

Bosnalijek d.d. Jukićeva 53, Sarajevo, Bosnia and Herzegovina