

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### SOLTRIK

100 mg / 5 mL, oral suspension

MEBENDAZOLE

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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.*

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*• 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 Soltrik is and what it is used for
2. Before you take Soltrik
3. How to take Soltrik
4. Possible side effects
5. How to store Soltrik
6. Further information

#### 1. WHAT SOLTRIK IS AND WHAT IT IS USED FOR

Soltrik, oral suspension, belongs to the group of medicines called anthelmintics (antiparasitics) and contains mebendazole as the active substance. The medicine has a wide range of effects and destroys parasites in a way that disrupts their feeding. It is used in treatment of infections caused by intestinal parasites belonging to the group of cylindrical worms (small and large children's worm, the other roundworms):

- enterobiasis
- other parasite infections and mixed infections (ascariasis, trichuriasis, ancylostomiasis, necatoriasis)

Soltrik is used in adults and children older than 2 years. If you or your child have an infection of intestines because of the presence of those parasites (worms) doctor will suggest that you take a medicine Soltrik.

Infections worms are common, they can occur in anyone and it does not indicate poor hygiene of your household and the household members.

If you want to get more information about the disease and your condition, talk to your doctor.

## 2. BEFORE YOU TAKE SOLTRIK

### **Do not take Soltrik:**

- if you are allergic to mebendazole or any other component of the medicine (see section 6);
- during pregnancy.

Do not use the medicine Soltrik if any of these apply to you. If in the course of administration you notice any allergic reaction stop taking the medicine and consult a doctor. If you are not sure, talk to your doctor or pharmacist before using the medicine.

### **Take special care with Soltrik:**

Soltrik is not used in the treatment of children under the age of 2 years.

General measures:

In order to prevent the emergence and spread of the infection in your family, as well as re-infection, it is necessary to comply with the following hygiene measures the minimum 6 weeks of initiation of therapy:

- Regularly cut nails.
- Avoid nail biting and thumb sucking.
- Wear pajamas or underwear during sleep.
- Every morning thoroughly wash anal region (the area around the anus).
- Each person in the family should use their own towels.
- Regularly change clothes.
- Regularly wash and iron linens.
- Wash hands and nails after using the toilet and before every meal.

Additional information about the parasite:

Children worm (*Enterobius vermicularis*) produces a large number of small eggs. It can be present in house dust, in clothes, carpets, towels and bedding. You can get in touch with someone who already has the worms. Since the eggs are extremely small, it is easy to swallow them and then it passes into the intestine, where they grow into worms. Females lay their eggs at night around the anus. This is what causes the itching of "buttocks" and leads to scratching. The eggs are then transferred to the fingers and nails, and can easily enter the mouth due to thumb sucking or biting your nails. The lifespan of the adult parasites is 6 weeks, so it is necessary to comply with the hygiene measures during that period.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Be sure to tell your doctor if you are treated with any of the following medicines:

- metronidazole - used for certain bacterial and protozoal infections;
- cimetidine - applied to the excessive production of acid in the stomach.

### **Taking food and drink with SOLTRIK**

The presence of food in the stomach improves the medicine absorption.

### **Pregnancy and breastfeeding**

Do not take medicine Soltrik if you are pregnant; think you might be pregnant or planning to become pregnant.

The medicine should not be used during the period of breast-feeding, because the amount of medicines found in breast milk.

Before taking any medicine, consult your doctor or pharmacist. Sure, tell your doctor if you are pregnant, planning to become pregnant or if you are breast-feeding.

### ***Driving and using machines***

There are no known effects.

### ***Other warnings***

In case of intolerance to some sugars, contact your doctor before using this medicine because it contains sucrose and glucose.

Soltrik can cause allergic reactions, even delayed, because it contains Methylparahydroxybenzoate and Propylparahydroxybenzoate.

The medicine contains color Allura red AC, which can cause allergic reactions.

## ***3. HOW TO TAKE SOLTRIK***

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

The medicine is administered orally.

Before each use shake the bottle well.

For administration use a small stick (5 mL) enclosed within the package.

Children should always be under supervision when taking the medicine. It is not necessary to take any special measures in terms of changes in eating habits or to apply laxatives (means for bowel movements). It is necessary to adhere to recommended hygiene measures the minimum 6 weeks of initiation of therapy (see section 2).

Dose of the medicine Soltrik is the same for adults and children over 2 years. Dose depends on the type of parasite to be treated.

Adults and children older than 2 years:

Enterobiasis:

- 5 mL (1 teaspoon) of the suspension in the evening. A single dose of medicine should destroy all the worms. In the case of reinfection (reinfection), your doctor may recommend that you repeat the same dose after 2 weeks.

Other parasite infections and mixed infections (ascariasis, trihurijaza, ancylostomiasis, nekatorijaza)

- 5 mL (1 teaspoonful) of the suspension twice a day (morning and evening) for three consecutive days.

### ***If you take more Soltrik than you should***

Contact your doctor or pharmacist straight away.

### ***If you forget to take Soltrik***

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

If you have any further questions about the application of Soltrik, talk to your doctor or pharmacist.

## ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, Soltrik may cause side effects.

Stop taking the medicine and call your doctor at the nearest emergency center if you notice any of the following serious side effects:

- sudden swelling of the face and throat, urticaria (hives), irritation, redness and blistering of the skin. These signs may indicate the occurrence of a severe allergic reaction;
- occurrence of blisters on the skin, in the mouth, eyes, and in the genital area;
- seizures (muscle spasms).

Tell your doctor as soon as possible if you notice any of the following adverse reactions that occur:

**Common (occur at 1-10 on 100 patients taking the medicine):**

- abdominal pain.

**Uncommon (occur at 1-10 per 1,000 patients taking the medicine)**

- stomach discomfort;
- diarrhea
- gases.

**Rare (occur at 1-10 on 10,000 patients taking the medicine)**

- rash;
- severe skin lesions (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- inflammation of the liver;
- changes in liver enzyme values (can be determined by a blood test);
- reduced the number of white blood cells (can be determined by analyzing the blood), resistance to infection;
- unusual hair loss;
- dizziness.

If you notice any side effect, talk to your doctor or pharmacist.

## 5. HOW TO STORE SOLTRIK

Keep out of reach and sight of children.

Store the medicine at a temperature below 25° C, protected from light.

Shelf life after first opening: After first opening, keep at temperature below 25 ° C in the original packaging (to protect from light), no longer than 21 days.

Shelf life: 3 years.

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

## 6. FURTHER INFORMATION

### **What does Soltrik contain?**

**Active substance:** 5 ml of oral suspension contains 100 mg of mebendazole.

**The other ingredients:**

cellulose, dispersible;  
 xanthan gum;  
 Methylparahydroxybenzoate (E218);  
 Propylparahydroxybenzoate (E216);  
 sucrose;  
 glucose, liquid;  
 propylene glycol;  
 glycerol;  
 disodium edetate;

silicone defoamer 40%;  
polysorbate 85;  
sodium citrate;  
citric acid monohydrate Strawberry flavor 52312;  
colors Allura red AC CI 16035 (E129);  
purified water.

***Pharmaceutical form:***

Oral Suspension

***Pharmacotherapeutic group:***

Anthelmintics

***What Soltrik looks like and contents of the pack***

Appearance: Oral Suspension light pink in color, with the smell of strawberries.

Packaging: Bottle of cast glass, brown, III hydrolytic group, with a cap of high density polyethylene, with thread, white, with a safety ring and transparent cartridge of low density polyethylene.

Spoon of is made of white polyethylene, volume of 5 mL.

The bottle with measuring spoon is packaged in a folding box.

***Regime of dispensing***

The medicine is issued on prescription.

***Manufacturer***

Galenika ad, Batajnički drum bb, 11080 Belgrade, Serbia