PATIENT INFORMATION

LIKMEZ® (lik mez) (metronidazole) oral suspension

What is LIKMEZ?

LIKMEZ is an antibiotic medicine used to treat:

- trichomoniasis (a sexually transmitted infection) in adults
- amebiasis (an infection caused by a parasite) in adults and children
- anaerobic bacterial infections (infections caused by bacteria that do not need oxygen to survive) in adults

It is not known if LIKMEZ is safe and effective in children, except for the treatment of amebiasis.

Do not take LIKMEZ if you:

- are allergic to metronidazole or other nitroimidazole medicines.
- have taken disulfiram (medicine used to help people stop drinking alcohol) in the last 2 weeks. Taking LIKMEZ with disulfiram can cause psychotic symptoms (seeing or hearing things that are not really there) in people who drink alcohol.
- drink alcohol or use products with propylene glycol during treatment with LIKMEZ and for at least 3 days after you stop taking LIKMEZ, because this can cause side effects including abdominal cramps, nausea, vomiting, headaches, and flushing.
- have Cockayne Syndrome (a rare genetic disorder that affects growth and development).

Before taking LIKMEZ, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems.
- have kidney problems.
- have medical problems that affect the brain.
- have a yeast infection.
- · have a history of blood problems.
- are breastfeeding or plan to breastfeed. LIKMEZ can pass into your breastmilk. Talk to your healthcare provider about the
 best way to feed your baby while taking LIKMEZ. If you are breastfeeding, you may consider pumping and throwing away
 your breast milk during treatment with LIKMEZ and for 48 hours after your last dose of LIKMEZ and feeding your infant stored
 human milk or formula.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. LIKMEZ and other medicines can affect each other causing side effects.

Especially tell your healthcare provider if you take:

- warfarin or other blood thinners (anticoagulants)
- lithium
- busulfan
- cimetidine
- phenytoin and phenobarbital

You can ask your pharmacist for a list of medicines that interact with LIKMEZ.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take LIKMEZ?

- Take LIKMEZ exactly as your healthcare provider tells you to.
- Shake LIKMEZ oral suspension well before each use.
- Always use an accurate measuring device to measure the correct amount of LIKMEZ. Do not use a household teaspoon or tablespoon to measure your medicine. You can ask your pharmacist for the measuring device you should use and how to measure the correct dose.
- Do not skip any doses of LIKMEZ or stop taking it, even if you begin to feel better, until you have finished your prescribed treatment. Taking all of your LIKMEZ doses will help make sure that all of the bacteria are killed. Taking all of your LIKMEZ doses will help lower the chance that the bacteria will become resistant to LIKMEZ. If you become resistant to LIKMEZ, LIKMEZ and other antibacterial medicines may not work for you in the future.
- If you take too much LIKMEZ, call your healthcare provider or go to the nearest emergency room right away.

What are the possible side effects of LIKMEZ?

LIKMEZ may cause serious side effects including:

- Severe skin reactions. Serious skin reactions that may affect any part of the body and can lead to death, including toxic epidermal necrolysis (TEN), Stevens-Johnson Syndrome (SJS), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP), have happened in some people taking metronidazole (the active ingredient in LIKMEZ). These severe skin reactions may be life threatening and you may need to be treated in a hospital. Stop taking LIKMEZ right away and call your healthcare provider or get emergency help if you have any of the following symptoms:
 - skin rash or acne
 - dry skin
 - itching
 - blisters on your skin
 - redness or swelling of your face, hands, or soles of your feet
- blisters or sores in your mouth
- peeling of your skin
- fever
- muscle or joint aches
- swollen glands
- **Nervous system problems**, including brain disorder (encephalopathy), inflammation of the brain and spinal cord membranes (aseptic meningitis), numbness or tingling in the hands or feet (peripheral neuropathy) and seizures (convulsions). Tell your healthcare provider right away if you have any nervous system problems while taking LIKMEZ.
- Worsening yeast infection (candidiasis) symptoms in people with a known yeast infection or a yeast infection they were not aware of.
- Low white blood cell count (leukopenia) in people with a history of blood problems. This can affect how well the body fights infection.

The most common side effects of LIKMEZ include: nausea, headache, anorexia, vomiting, diarrhea, pain in the upper abdomen, abdominal cramping, and constipation.

Other side effects of LIKMEZ include:

- allergic reactions: such as itching, hives (urticaria), flushing of the skin, red skin rash that can be widespread, blisters and separation of skin layers, nasal congestion, dryness of the mouth and vagina, and fever
- abnormal heart rhythm (QT prolongation)

These are not all the possible side effects of LIKMEZ. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LIKMEZ?

- Store LIKMEZ oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze.
- Throw away (discard) any unused LIKMEZ 60 days after opening the container.

Keep LIKMEZ and all medicines out of the reach of children.

General information about the safe and effective use of LIKMEZ.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LIKMEZ for a condition for which it was not prescribed. Do not give LIKMEZ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about LIKMEZ that is written for health professionals.

What are the ingredients in LIKMEZ?

Active ingredient: metronidazole

Inactive ingredients: glycerin, magnesium aluminum silicate, methylparaben, microcrystalline cellulose, natural peppermint flavor, natural strawberry flavor, propylparaben, purified water, sodium phosphate dibasic, sodium phosphate monobasic, sucralose, and sucrose.

Manufactured by:

Saptalis Pharmaceuticals, LLC.

Hauppauge, NY 11788

Made in USA

For more information, call 1-833-727-8254.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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