

FDA-Approved Patient Labeling

ONMEL (itraconazole)

Read this Patient Information before you start using ONMEL and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about ONMEL?

ONMEL can cause serious life-threatening side effects, including:

1. Heart Failure. Do not take ONMEL if you have had heart failure, including congestive heart failure.

Stop taking ONMEL and call your doctor right away if you have any of these symptoms of congestive heart failure:

- shortness of breath
- swelling of your feet, ankles, or legs
- sudden weight gain
- increased tiredness
- coughing up white or pink phlegm
- fast heartbeat
- waking up at night more than normal for you

2. Serious cardiovascular effects. Do not take ONMEL if you also take the following medicines:

- cisapride (Propulsid)
- pimozone (Orap)
- quinidine (Quindine Gluconate, Quindine Sulfate)
- dofetilide (Tikosyn)
- levomethadyl (Oralam)
- midazolam (Versed)
- felodipine, nisoldipine (Lexxel, Plendil, Sular)
- triazolam (Halcion)
- lovastatin (Mevacor, Advicor, Altoprev)
- simvastatin (Zocor, Simcor, Vytorin)
- ergot alkaloids (Migranal, Ergonovine, Cafergot, Methergine, Dihydroergotamine Mesylate, Methylergonovine)
- methadone (Dolophine)

This is not a complete list of medicines that can interact with ONMEL.

- Before taking ONMEL, tell your doctor about all the medicine you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.
- Before you start any new medicine, ask your doctor or pharmacist if it is safe to take it with ONMEL.

What is ONMEL?

ONMEL is a prescription medicine used to treat fungal infections of the toenails. It is not known if ONMEL is safe and effective in children under the age of 18.

Who should not take ONMEL?

Do not take ONMEL if you:

- have or had heart failure, including congestive heart failure.
- Take certain medicines. See “What is the most important information I should know about ONMEL?”
- are pregnant or plan to become pregnant. ONMEL can harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- have ever had an allergic reaction to itraconazole or any of the other ingredients in ONMEL. Ask your doctor or pharmacist for a list of these ingredients.

What should I tell my doctor before taking ONMEL?

Before taking ONMEL, tell your doctor if you:

- have or had heart, lung, liver or kidney problems
- have any other medical conditions
- **are pregnant or planning to become pregnant.** See “Who should not take ONMEL?”. Females who can become pregnant should use effective birth control during treatment with ONMEL and for 2 months after you stop

treatment with ONMEL. Talk to your doctor about the type of birth control that is best for you while taking ONMEL.

- are breast-feeding or plan to breast-feed. ONMEL can pass into your breastmilk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take ONMEL.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking ONMEL with certain other medicines could lead to serious or life-threatening medical problems.

- See **“What is the most important information I should know about ONMEL?”**
- **Fentanyl. Taking fentanyl, a strong opioid narcotic main medicine with ONMEL could cause serious breathing problems that can lead to death.**

Talk to your doctor or pharmacist before you start any new medicine. They can tell you if it is safe to take ONMEL with your other medicines.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take ONMEL?

Take ONMEL exactly as prescribed by your doctor. Be sure to finish all of your ONMEL as prescribed by your doctor.

- ONMEL comes in a 14 tablet blisterpack container.
- Take ONMEL with a full meal at the same time each day.
- Your doctor should do blood tests to check your liver function before you start and while you take ONMEL, especially if you have liver problems.
- If you forget to take or miss doses of ONMEL, skip that dose and take the next dose at your regular time. Do not make up missed doses.
- If you take too many ONMEL, call your local poison control center or go to the nearest hospital emergency room right away.

What are the possible side effects of ONMEL?

ONMEL can cause serious side effects, including:

- See **“What is the most important information I should know about ONMEL?”**
- **liver failure and death. Stop taking ONMEL and call your doctor right away if you have symptoms of liver failure including:**
 - unusually tired
 - lose your appetite
 - nausea
 - abdominal pain
 - vomiting
 - yellow change in the color of your skin or eyes
 - dark colored urine
 - pale stools (bowel movements)
- **nerve damage** (neuropathy). Call your doctor right away if you have tingling or numbness in your hands or feet. You may need to stop taking ONMEL if this happens.
- **hearing loss.** Hearing loss can happen for a short time or permanently in some people who take ONMEL with other medications. Stop taking ONMEL and call your doctor right away if you have any changes in your hearing.

Common side effects of ONMEL include:

- increased liver enzyme in blood test results
- upper respiratory infection or cold (runny nose, cough and sneeze)
- urinary tract infection (burning and painful urination)
- stomach pain
- diarrhea
- nausea
- headache
- tiredness
- throat pain
- back pain

These are not all of the possible side effects of ONMEL. Tell your doctor if you any side effect that bothers you or that does not go away. For more information, ask your doctor.

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 ONMEL?

- Store at controlled room temperature between 59° to 77°F (15° to 25°C).
- Keep ONMEL away from light and moisture.
- Keep ONMEL and all medicines out of reach of children.

General Information:

Medicines are sometimes prescribed for conditions that are not mentioned in Patient Information leaflets. Do not use ONMEL for a condition for which it was not prescribed. Do not give ONMEL to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about ONMEL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ONMEL that is written for health professionals.

For more information about ONMEL call 1-877-743-8454.

What are the ingredients in ONMEL?

Active ingredient: itraconazole

Inactive ingredients: colloidal silicon dioxide, crospovidone, hydrogenated vegetable oil, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, propylene glycol, talc, and titanium dioxide.

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What happens if I have a fungal nail infection?

Anyone can have a fungal nail infection, but it is usually found in adults. When a fungus infects the nail, the infected part of the nail may turn yellow or brown. If not treated, the fungus may spread, and more of the nail may change color, may become thick or brittle, and the tip of the nail may become raised. In some patients, this can cause pain and discomfort.

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