



Impavido[®]
 (miltefosine) capsules
 for oral use

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MEDICATION GUIDE
IMPAVIDO[®] (Im-PA-vee-do)
(miltefosine)
capsules, for oral use

Read this Medication Guide before you start taking IMPAVIDO and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

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

IMPAVIDO may cause serious risks to pregnancy:

- **Do not** take IMPAVIDO if you are pregnant. If you take IMPAVIDO during pregnancy, your baby is at risk for death or serious birth defects. If you become pregnant while taking IMPAVIDO, stop taking IMPAVIDO and talk to your healthcare provider right away if you become pregnant during treatment with IMPAVIDO.
- You should have a pregnancy test before you start taking IMPAVIDO.
- Women who can become pregnant should use effective birth control (contraception) during IMPAVIDO treatment and for 5 months after their last dose of IMPAVIDO. Talk to your healthcare provider about which birth control method is right for you.
- **Pregnancy Registry:** There is a registry for women who become pregnant during treatment with IMPAVIDO. If you become pregnant or think you may be pregnant while taking IMPAVIDO, tell your healthcare provider right away. Talk to your healthcare provider about registering with the IMPAVIDO Pregnancy Registry. The purpose of this registry is to collect information about your health and your baby's health. Your healthcare provider can enroll you in this registry by calling 1-866-588-5405 or by going to <http://www.impavido.com/motherregistry>.

What is IMPAVIDO?

IMPAVIDO is prescription medicine used to treat certain types of leishmaniasis in adults and children 12 years of age and older weighing 66 pounds or more with:

- visceral leishmaniasis (affecting your internal organs) caused by *Leishmania donovani*
- cutaneous leishmaniasis (affecting the skin) caused by *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*
- mucosal leishmaniasis (affecting the nose, mouth and throat) caused by *Leishmania braziliensis*

It is not known if IMPAVIDO is safe and effective in other types of leishmaniasis.

It is not known if IMPAVIDO is safe and effective in children under 12 years of age.

Do not take IMPAVIDO if you:

- **are pregnant, plan to become pregnant, or become pregnant during treatment with IMPAVIDO. See "What is the most important information I should know about IMPAVIDO?"**
- have Sjögren-Larsson syndrome
- are allergic to miltefosine or any of the ingredients in IMPAVIDO. See the end of this Medication Guide for a complete list of the ingredients in IMPAVIDO.

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

- have kidney or liver problems. Your healthcare provider should do blood tests to check your kidneys and liver before you start, during and after your treatment with IMPAVIDO.
- are breastfeeding or plan to breastfeed. It is not known if IMPAVIDO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take IMPAVIDO. You should not breastfeed while you take IMPAVIDO and for 5 months after your last dose of IMPAVIDO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.





How should I take IMPAVIDO?

- Take IMPAVIDO exactly as your healthcare provider tells you to.
- Complete your full 28-day IMPAVIDO treatment.
- Take IMPAVIDO capsules whole. Do not break, crush, dissolve, or chew IMPAVIDO before swallowing.
- Take IMPAVIDO with food to help reduce stomach problems.

What are the possible side effects of IMPAVIDO?

IMPAVIDO may cause serious side effects, including:

See "What is the most important information I should know about IMPAVIDO?"

- **possible fertility problems.** When used in both male humans and animals, IMPAVIDO decreased semen quality, sperm count and semen volume (the amount of fluid released upon ejaculation). IMPAVIDO may cause fertility problems in males. It is not known how long these problems may last.

When used in female animals, IMPAVIDO caused abnormal changes to their menstrual cycles. IMPAVIDO may cause fertility problems in females.

Talk to your healthcare provider if fertility problems are a concern for you.
- **decreased effectiveness of oral contraceptive pills.** If you take birth control pills, vomiting, diarrhea or both may cause your birth control pills to be less effective at preventing pregnancy. If you have vomiting, diarrhea, or both together while taking IMPAVIDO, use an additional non-oral method of birth control, such as male condoms with spermicide, until you are no longer having vomiting or diarrhea, but do not stop taking IMPAVIDO. Talk with your healthcare provider if you have questions about birth control methods that may be right for you during this time.
- **testicular pain and absent or decreased ejaculation.**
- **kidney problems.** Your healthcare provider will do tests every week and for 4 weeks after your treatment with IMPAVIDO has ended to check your kidneys.
- **liver problems.** Your healthcare provider will do tests to check your liver while you are taking IMPAVIDO.
- **stomach problems.** IMPAVIDO can cause vomiting, diarrhea, and dehydration. Call your healthcare provider right away if you have severe vomiting and diarrhea that does not go away. Drink a lot of fluids to help prevent dehydration or kidney problems if you are having vomiting and diarrhea.
- **decreased platelet count (thrombocytopenia).** Some people who were treated for visceral leishmaniasis had decreased platelets. If you have visceral leishmaniasis, your healthcare provider will check your platelet count while you are taking IMPAVIDO. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with IMPAVIDO. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- **severe skin reactions.** IMPAVIDO can cause a rare but serious skin reaction called Stevens-Johnson Syndrome. This may need to be treated in a hospital and may be life-threatening. If you develop a skin rash with blisters, peeling rash, sores in the mouth, hives or any other allergic reactions while taking IMPAVIDO, stop taking IMPAVIDO. Call your healthcare provider right away or get emergency help.

The most common side effects of IMPAVIDO include:

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| • nausea | • vomiting | • diarrhea | • stomach pain |
| • decreased appetite | • dizziness | • headache | • sleepiness |
| • skin itching | • abnormal liver test | • abnormal kidney tests | • motion sickness |
| • fever | • tiredness | • weakness | • enlarged lymph nodes |

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

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 IMPAVIDO?

- Store IMPAVIDO at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect IMPAVIDO from moisture.

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

General information about the safe and effective use of IMPAVIDO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use IMPAVIDO for a condition for which it was not prescribed. Do not give IMPAVIDO 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 IMPAVIDO that is written for health professionals.

What are the ingredients in IMPAVIDO?

Active ingredient: miltefosine

Inactive ingredients: colloidal silicon dioxide, microcrystalline cellulose, lactose monohydrate, talc, and magnesium stearate. The capsule shell contains gelatin, titanium dioxide, ferric oxide, and purified water.

Distributed by: Profounda, Inc.

PR034-01

For more information, go to www.IMPAVIDO.com or www.dailymed.nlm.nih.gov, or call 1-866-588-5405.

