

PATIENT INFORMATION
VIVJOA™ [viv joe ah]
(oteseconazole)
capsules, for oral use

What is VIVJOA?

- VIVJOA is a prescription medicine used to reduce the risk of vaginal yeast infections that keep coming back (recurrent vulvovaginal candidiasis, RVVC) in females with a history of RVVC.
- VIVJOA should only be taken by females who are not pregnant and who are not able to become pregnant. It is not known if VIVJOA is safe and effective in females who have not had their first menstrual period.

Do not take VIVJOA if you:

- Are able to become pregnant.
- Are pregnant or plan to become pregnant. VIVJOA may harm your unborn baby. Tell your doctor if you are pregnant, think you might be pregnant, or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. It is not known if VIVJOA passes into your breastmilk.
- Are allergic to oteseconazole or any of the ingredients in VIVJOA. See the end of this Patient Information leaflet for a complete list of ingredients in VIVJOA.

Before you take VIVJOA, tell your doctor about all of your medical conditions, including if you:

- have kidney problems
- have liver problems

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

Especially tell your doctor if you take medicines called breast cancer resistance protein (BCRP) transporter substrates, including the cholesterol lowering medicine rosuvastatin. Ask your doctor or pharmacist for a list of these medicines if you are not sure. Taking VIVJOA (a BCRP inhibitor) with BCRP transporter substrates may increase the risk of side effects with these medicines.

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

How should I take VIVJOA?

- **Your doctor has prescribed VIVJOA:**
 - Take VIVJOA exactly as your doctor tells you to take it. Talk to your doctor if you have any questions.
 - On **Day 1:** Take **VIVJOA 600 mg** (four capsules as a single dose), by mouth then,
 - On **Day 2:** Take **VIVJOA 450 mg** (three capsules as a single dose), by mouth then,
 - On **Day 14:** Take **VIVJOA 150 mg** (one capsule) **one time a week** (every 7 days) by mouth for 11 weeks.
- Take VIVJOA capsules by mouth with food.
- Swallow VIVJOA capsules whole. Do not chew, crush, dissolve, or open the capsules.

What are the possible side effects of VIVJOA?

- See “**Do not take VIVJOA if you:**” Females who are pregnant, are able to become pregnant, and females who are breastfeeding should not take VIVJOA.

The most common side effects of VIVJOA are headache and nausea.

These are not all the possible side effects of VIVJOA. For more information, ask your doctor or pharmacist.

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 VIVJOA?

- Store VIVJOA at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light when removed from the outer carton.

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

General information about the safe and effective use of VIVJOA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VIVJOA for a condition for which it has not been prescribed. Do not give VIVJOA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about VIVJOA that is written for health professionals.

What are the ingredients in VIVJOA?

Active Ingredient: oteseconazole

Inactive Ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose, magnesium stearate, silicified microcrystalline cellulose, and sodium lauryl sulfate. Capsule shell and print constituents: FD&C Blue #1, FD&C Red #3, gelatin, Opacode SW-9008/SW-9009 and titanium dioxide.

VIVJOA does not contain gluten (wheat, barley, or rye).

Manufactured for and Distributed by:

Mycovia Pharmaceuticals, Inc.
Durham, NC 27703

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For more information, go to www.mycovia.com or call 1-855-299-0637.

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

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