VIVJOA™ (oteseconazole) capsules are the first and only FDA-approved medication for recurrent vulvovaginal candidiasis (RVVC)

This resource was developed to assist healthcare professionals and their office staff to complete prior authorizations for VIVJOA. The information in this resource covers general requirements for coverage of VIVJOA. Coverage will vary by payer. The information provided represents no guarantee of coverage or reimbursement. Healthcare professionals may work with individual patient plans to confirm what information they require.

Prior Authorization Considerations

VIVJOA is likely to require prior authorization (PA) from the patient's health plan. Detailed clinical documentation may help expedite payer approval for VIVJOA. Consider using the following checklist when you are preparing a PA for VIVJOA.

√ Does the patient meet the criteria for **a diagnosis of recurrent vulvovaginal candidiasis (RVVC)**?
- Verification of **at least 2 previous episodes of VVC in the past 12 months**?
- What **symptoms** did the patient exhibit?

√ Is the patient a female who is **NOT of reproductive potential** including:
- Postmenopausal women
- Hysterectomy
- Tubal ligation
- Salpingo-oophorectomy
- Other reasons/conditions for permanent infertility

√ Verification of previous treatment with **any prescription and/or OTC product**?

- **Prior to sending prior authorization, ensure that the appropriate form is used.**
- **Be sure to include documentation of the patient's medical history and all relevant diagnosis codes.**
- **Provide all clinical documentation, including prior diagnoses, laboratory results, and previous therapies.**

INDICATION

VIVJOA™ (oteseconazole) is indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Females of Reproductive Potential: VIVJOA is contraindicated in females of reproductive potential. Females who are NOT of reproductive potential are defined as: persons who are biological females who are postmenopausal or have another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy).

Pregnant and Lactating Women: VIVJOA is contraindicated in pregnant and lactating women.

Hypersensitivity: VIVJOA is contraindicated in patients with known hypersensitivity to oteseconazole.

Please see additional Important Safety Information on next page and full Prescribing Information.

vivjoa™
(oteseconazole capsules)
150 mg per capsule, for oral use

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity: Based on animal studies, VIVJOA may cause fetal harm. The drug exposure window of approximately 690 days (based on 5 times the half-life of oteseconazole) precludes adequate mitigation of the embryo-fetal toxicity risks. Advise patients that VIVJOA is contraindicated in females of reproductive potential, and in pregnant and lactating women because of potential risks to a fetus or breastfed infant.

ADVERSE REACTIONS

The most frequently reported adverse reactions among VIVJOA-treated patients in clinical studies included headache (7.4%) and nausea (3.6%).

DRUG INTERACTIONS

Effect of VIVJOA on Other Drugs: Oteseconazole is a Breast Cancer Resistance Protein (BCRP) inhibitor. Concomitant use of VIVJOA with BCRP substrates (e.g., rosuvastatin) may increase the exposure of BCRP substrates (e.g., rosuvastatin), which may increase the risk of adverse reactions associated with these drugs. Use the lowest possible starting dose of the BCRP substrate or consider reducing the dose of the substrate drug and monitor for adverse reactions.

USE IN SPECIFIC POPULATIONS

Pregnancy: VIVJOA is contraindicated in females of reproductive potential and in pregnant women. Based on animal studies, VIVJOA may cause fetal harm when administered to pregnant women. In addition, the drug exposure window of approximately 690 days (based on 5 times the half-life of oteseconazole) precludes adequate mitigation of the embryo-fetal toxicity risks.

Lactation: VIVJOA is contraindicated in lactating women and females of reproductive potential. There are no data on the presence of oteseconazole in human or animal milk or data on the effects of oteseconazole on milk production. There were no reported adverse effects in breastfed infants following maternal exposure to oteseconazole during lactation; however, given the limited duration of follow-up of the oteseconazole-exposed infants during the post-natal period, no conclusions can be drawn from these data.

Females of Reproductive Potential: VIVJOA is contraindicated in females of reproductive potential based on data from rat studies.

Pediatric Use: The safety and effectiveness of VIVJOA have not been established in pre-menarchal pediatric females.

Geriatric Use: Clinical studies of VIVJOA did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.

Renal Impairment: No dosage adjustment of VIVJOA is recommended in patients with mild to moderate renal impairment. VIVJOA is not recommended for use in patients with severe renal impairment or end-stage renal disease, as clinical studies did not include sufficient numbers of these patients.

Hepatic Impairment: No dosage adjustment of VIVJOA is recommended in patients with mild hepatic impairment. VIVJOA is not recommended for use in patients with moderate or severe hepatic impairment, as there is insufficient information in these patients.

To report SUSPECTED ADVERSE REACTIONS, contact Mycovia Pharmaceuticals, Inc. at 1-855-299-0637 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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mycovia Pharmaceuticals

04/2022
MA-594-2022-v1

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