

Drug Review: Oteseconazole

Registrations: It had been registered in the following countries: United Kingdom (U.K.), United States of America (USA), Canada, and Saudi Arabia (SA).

Trade name (USA.):** VIVJOA[®]

Registration number (S.A.):** Not available

Insurance Drug Formulary (S.A.):** Not available

General Information:

Registered Company: Mycovia Pharmaceuticals, Inc.

Regulatory Status: R.X.

Mechanism of Action:

Inhibitor targeting the fungal sterol by inhibition of CYP51 results accumulation of 14-methylated sterols, which are toxic to fungi.

Indication:

Candidal vulvovaginitis.

Approved (Labeled) indication: Candidal vulvovaginitis.

Route of Administration: Oral.

Dosage Forms: Oral Capsule: 150 MG.

Dosing/Administration:

Administer orally with food. Swallow the capsules whole; do not chew, crush, dissolve, or open the capsules.

Dose: (Oteseconazole monotherapy regimen) 600 mg orally on day one as a single dose, followed by 450 mg orally on day two as a single dose; On day 14, administer 150 mg orally once every seven days for 11 weeks.

(Oteseconazole/fluconazole combination regimen) Fluconazole 150 mg orally on days 1, 4, and 7, then oteseconazole 150 mg once daily on days 14 to 20, then on day 28, administer 150 mg oteseconazole once every seven days for 11 weeks.

Dose in Renal/Hepatic failure: Not recommended to use.

Geriatric Dose: Safety and effectiveness not established in geriatric patients.

Indicated for pediatrics: Safety and effectiveness not established in pediatric patients.

Pharmacokinetic: Absorption

- T_{max}, oral: 5 to 10 hr.
- Effects of food: AUC increased by 36%.

Distribution

- Protein binding: 99.5% to 99.7% (plasma proteins).
- V_d: 423 L.

Metabolism

- Oteseconazole does not undergo significant metabolism.

Excretion

- Renal excretion: 26%.
- Fecal/biliary excretion: 56%.

Elimination Half-Life

- 138 days.

Safety:

Common Adverse Reactions (%): Nausea, Headache.

Severe/rare adverse Reactions (%): Intermenstrual bleeding, Menorrhagia.

Drug Interactions:

- Oteseconazole has serious interactions with the following drugs:
- Pitavastatin.
- Rimegepant.
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- rimegepant.

Oteseconazole interacts moderately with at least 37 other drugs, such as amiodarone and amlodipine.

Contraindications/Precautions:

Contraindications:

- Females of reproductive potential.
- Pregnant and lactating women.
- Known hypersensitivity to any component of the product.

Precautions: Not recommended to use in hepatic or renal impairment.

Monitoring Requirements:

- 1) Elimination of positive blood or tissue mycological cultures may indicate efficacy.
- 2) Obtain fungal cultures prior to treatment initiation (although treatment may be started before results are received).

Sound-Alikes/ Look-Alikes: Not available.

High Alert: Not available.

Boxed warnings or alerts issue: Not available.

Toxicity if antidote required: Not available.

Storage if there is a special condition: Store at a controlled room temperature between 20 - 25°C. Protect from light.

Patient counseling

1. Instruct patients to avoid pregnancy during the drug therapy course.
2. Advise the patient to take the medication with food.

Cost Analysis

Drugs	Drug classes	Approval Indication	Dose	Cost	Insurance drug formulary (SCHI)
Oteseconazole	Antifungal Anti-Infective Agent	Candidal vulvovaginitis	600 mg orally on day one as a single dose, followed by 450 mg orally on day two as a single dose; On day 14, administer 150 mg orally once every seven days for 11 weeks.	via oral capsule, 150 mg is around \$2,966 for a supply of 18 capsules.	Not covered (11.6.2023)
Fluconazole	Antifungal Anti-Infective Agent	<ul style="list-style-type: none"> Bone marrow transplant - Candidiasis; Prophylaxis Candidal vulvovaginitis Candidiasis of the esophagus Candidiasis of urogenital site Cryptococcal meningitis Cryptococcal meningitis - HIV infection Oropharyngeal candidiasis. 	candida vulvovaginitis <ul style="list-style-type: none"> (Uncomplicated) 150 mg orally as a single dose (FDA and guideline dosage). 	Average retail price of \$23.45 for one 150MG Tablet.	Covered
Ibexafungerp	Antifungal Anti-Infective Agent	Candidal vulvovaginitis	300 mg (two 150-mg tablets) orally twice daily for one day (approximately 12 hr apart) for a total dose of 600 mg (four 150-mg tablets).	Retail price of \$597	Not covered (11.6.2023)

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Received: 11-10-2022;

Accepted: 13-12-2021.

Access this article online	
	www.ijpcs.net
	DOI: 10.5530/ijpcs.2023.12.25