Otegal™

Oteseconazole INN150 mg

COMPOSITION
Otegal™ Capsule: Each capsule contains Oteseconazole INN 150 mg

PHARMACOLOGY
Oteseconazole is an azole metalloenzyme inhibitor targeting the fungal sterol, 14α demethylase (CYP51), an enzyme that catalyzes an early step in the biosynthetic pathway of ergosterol, a sterol required for fungal cell membrane formation and integrity. Inhibition of CYP51 results in the accumulation of 14-methylated sterols, some of which are toxic to fungi. Through the inclusion of a tetrazole metal-binding group, Oteseconazole has a lower affinity for human CYP enzymes.

INDICATION
Indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential.

DOSAGE & ADMINISTRATION
There are two recommended dosage regimens: An Oteseconazole only regimen and a Fluconazole/ Oteseconazole regimen. Use one of these two dosage regimens. Administer orally with food.

- ***For the Oteseconazole-only Dosage Regimen:***
  - ♦On Day 1: Administer 150 mg 4 capsules 600 mg (as a single dose), then
  - ♦On Day 2: Administer 150 mg 3 capsules 450 mg (as a single dose), then
  - ♦Beginning on Day 14: Administer 150 mg 1 capsule once a week (every 7 days) for 11 weeks (Weeks 2 through 12).

- ***For the Fluconazole/ Oteseconazole Dosage Regimen:***
  - ♦On Day 1, Day 4, and Day 7: Administer fluconazole 150 mg 1 capsule orally, then
  - ♦On Days 14 through 20: Administer 150 mg 1 capsule once daily for 7 days, then
  - ♦Beginning on Day 28: Administer 150 mg 1 capsule once a week (every 7 days) for 11 weeks (Weeks 4 through 14).

ADVERSE EFFECT
The most frequently reported adverse reactions (incidence > 2%) are headache and nausea.

CONTRAINDICATION
- Females of Reproductive Potential
- Pregnant and Lactating women
- Hypersensitivity to Oteseconazole

WARNING & PRECAUTION
Embryo-Fetal Toxicity: Based on animal studies, Oteseconazole 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 Oteseconazole is contraindicated in females of reproductive potential, and in pregnant and lactating women because of potential risks to a fetus or breastfed infant..

DRUG INTERACTION
BCRP (Breast Cancer Resistance Protein) Substrates: Concomitant use of Oteseconazole with BCRP substrates may increase the exposure of drugs that are BCRP substrates, 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 drugs and monitor for adverse reactions.

USE IN SPECIFIC POPULATIONS
Pregnancy: Oteseconazole is contraindicated in females of reproductive potential and in pregnant women.
Lactation: Oteseconazole is contraindicated in lactating women.
Pediatrics: The safety and effectiveness of Oteseconazole have not been established in pre-menarchal pediatric females.
Geriatric Use: Clinical studies of Oteseconazole 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: Not recommended in severe renal impairment or ESRD (with or without dialysis).
Hepatic Impairment: Not recommended in moderate or severe hepatic impairment.

STORAGE
Store below 30°C, in a dry place. Keep all medicines out of reach of children.

HOW SUPPLIED
Otegal™ Capsule: Each box containing 10 capsules in Alu-Alu blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS PLC.
BANGLADESH