SK+F
ESKAYEF PHARMACEUTICALS LTD.
Murapara, Rupganj, Narayanganj 1464, Bangladesh.

Packaging Material Code: R/PM1387
Version No.: V01

90 mm

190 mm

Olatab™

Olaparib INN Film Coated Tablet

DESCRIPTION

Olatab™ is a preparation of Olaparib. Olaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1, PARP2, and PARP3. PARP enzymes are involved in normal cellular functions, such as DNA transcription and DNA repair. Olaparib has been shown to inhibit growth of select tumor cell lines in vitro and decrease tumor growth in mouse xenograft models of human cancer, both as monotherapy or following platinum based chemotherapy. Increased cytotoxicity and anti-tumor activity following treatment with Olaparib were noted in cell lines and mouse tumor models with deficiencies in BRCA and non-BRCA proteins involved in the homologous recombination repair (HRR) of DNA damage and correlated with platinum response. In vitro studies have shown that Olaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes, resulting in DNA damage and cancer cell death.

INDICATIONS

- Ovarian cancer for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.
- Ovarian cancer for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.
- Breast cancer in patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment.

DOSAGE AND ADMINISTRATION

- To avoid substitution errors and overdose, do not substitute Olaparib tablets with Olaparib capsules on a milligram-to-milligram basis due to differences in the dosing and bioavailability of each formulation.
- Recommended tablet dose is 300 mg taken orally twice daily with or without food.
- Continue treatment until disease progression or unacceptable toxicity.
- For adverse reactions, consider dose interruption or dose reduction.
- For moderate renal impairment (CLcr 31-50 mL/min), reduce dose to 200 mg twice daily for total daily dose of 400 mg.

CONTRAINDICATIONS

None

SIDE EFFECTS

- Anemia, neutropenia, leukopenia.
- Nausea, vomiting, diarrhea, dyspepsia, decreased appetite, constipation and stomatitis.
- Fatigue (including asthenia), arthralgia/myalgia, dysgeusia, headache.
- Nasopharyngitis/upper respiratory tract infection/influenza, respiratory tract infection.

PRECAUTION AND WARNING

- **Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML):** Occurred in <1.5% of patients exposed to Olaparib monotherapy and the majority of events had a fatal outcome. Monitor patients for hematological toxicity at baseline and monthly thereafter. Discontinue if MDS/AML is confirmed.
- **Pneumonitis:** Occurred in <1% of patients exposed to Olaparib, and some cases were fatal. Interrupt treatment if pneumonitis is suspected. Discontinue if pneumonitis is confirmed.
- **Embryo-Fetal Toxicity:** Olaparib can cause fetal harm. Advise of the potential risk to a fetus and to use effective contraception.

DRUG INTERACTIONS

- **CYP3A Inhibitors:** Avoid concomitant use of strong CYP3A inhibitors such as Itraconazole, telithromycin, clarithromycin, ketoconazole, voriconazole, posaconazole, telaprevir or moderate CYP3A inhibitors such as amprenavir, apripitant, atazanavir, ciprofloxacin, crizotinib, diltiazem, erythromycin, fluconazole, imatinib, verapamil. If the inhibitor cannot be avoided, reduce the Olaparib dose.
- **CYP3A Inducers:** Avoid concomitant use of strong or moderate CYP3A inducers as decreased efficacy can occur.

USE IN PREGNANCY AND LACTATION

There are no available data on Olaparib use in pregnant women to inform the drug-associated risk. In an animal reproduction study, the administration of Olaparib to pregnant rats during the period of organogenesis caused teratogenicity and embryo-fetal toxicity.

No data are available regarding the presence of Olaparib in human milk, or on its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infants from Olaparib, advise a lactating woman not to breastfeed during treatment with Olaparib and for one month after receiving the last dose.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light & wet place. Keep out of reach of children.

PACKAGING

Olatab™ FCT: Each Box contains 3 strips having 10 tablets per strip. Each film coated tablet contains Olaparib INN 100 mg.

SK+F ONCOLOGY
Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM1387 V01

PM SPECIFICATION

Creative ID: CSD_02

Job Name: Olatab Insert		**Size:** L - 190 mm, W - 90 mm		**Paper:** 70 gsm Offset Paper
No. of Color: 2 Extra	**Pantone Color Code**	339 C	199 C	

	Creative Service Department	Marketing Department	PD/QC/Contract Customer	Approved By
Comments				
Signature & Date				