Olacent™

Olaparib Tablet

2051

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Presentation
Olacent™100: Each film coated tablet contains Olaparib INN 100 mg.
Olacent™150: Each film coated tablet contains Olaparib INN 150 mg.

Description
Olaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1, PARP2, and PARP3. PARP enzymes are involved in normal cellular homeostasis, such as DNA transcription, cell cycle regulation, 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. In vitro studies have shown that Olaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complex, resulting in disruption of cellular homeostasis and cell death.

Indication and usage
Olaparib is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:
- First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer
- First-line Maintenance Treatment of HRD-positive Advanced Ovarian Cancer in Combination with Bevacizumab
- Maintenance Treatment of Recurrent Ovarian Cancer
- Advanced Germline BRCA-mutated Ovarian Cancer After 3 or More Lines of Chemotherapy
- Germline BRCA-mutated HER2-negative Metastatic Breast Cancer
- First-Line Maintenance Treatment of Germline BRCA-mutated Metastatic Pancreatic Adenocarcinoma
- HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer

Dosage and administrations
- Recommended dosage is 300 mg taken orally twice daily with or without food.
- Patients receiving Olaparib for mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.
- For moderate renal impairment (CLcr 31-50 mL/min), reduce Olaparib dosage to 200 mg orally twice daily.

Warnings and precautions
- *Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML):* Occurred in approximately 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. Olaparib should be discontinued if MDS/AML is confirmed.
- *Pneumonitis:* Occurred in 0.8% of patients exposed to Olaparib, and some cases were fatal. Interrupt treatment if pneumonitis is suspected. Olaparib should be discontinued if pneumonitis is confirmed.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise of the potential risk to a fetus and to use effective contraception.
- Venous thromboembolic events including pulmonary embolism: occurred in 7% of patients with mCRPC. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate.

Contraindications
None.

Side-effects
Most common adverse reactions in clinical trials:
- As a single agent were nausea, fatigue (including asthenia), anemia, vomiting, diarrhea, decreased appetite, headache, neutropenia, dysgeusia, cough, dyspnea, dizziness, dyspepsia, leukopenia, thrombocytopenia, and upper abdominal pain.
- In combination with bevacizumab were nausea, fatigue (including asthenia), anemia, lymphopenia, vomiting, diarrhea, neutropenia, leukopenia, urinary tract infection, and headache.

Use in specific populations
Pregnancy: Olaparib can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. Olaparib wasteratogenic and caused embryo-fetal toxicity in rats at exposures below those in patients receiving the recommended human dose of 400 mg twice daily. If this drug is used during pregnancy, or if a patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for loss of the pregnancy.

Nursing Mothers: It is not known whether Olaparib is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Olaparib, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Pediatric Use: The safety and efficacy of Olaparib has not been established in pediatric patients.

Drug Interaction
- Strong or moderate CYP3A inhibitors: Avoid concomitant use. If concomitant use cannot be avoided, reduce Olaparib dosage.
- Strong or moderate CYP3A inducers: Avoid concomitant use.

Storage
Do not store above 30°C. Keep away from light and out of the reach of children.

Commercial pack
Olacent™100: Each box contains 2 blister strips of 10 tablets.
Olacent™150: Each box contains 2 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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