

Goparib™ 100

Olaparib Tablets 100 mg

Presentation: Each film-coated tablet contains: Olaparib.....100 mg
Excipients..... q.s.

Colors: Black Oxide of Iron, Yellow Oxide of Iron, and Titanium Dioxide I.P.

Goparib™ 150

Olaparib Tablets 150 mg

Presentation: Each film-coated tablet contains: Olaparib.....150 mg Excipients q.s.
Colors: Black Oxide of Iron, Yellow Oxide of Iron, and Titanium Dioxide I.P.

Pharmaceutical form: Film Coated Tablets for Oral Use Only.

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. 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. Pancreatic Cancer: Olaparib is indicated as monotherapy for the Maintenance treatment of adult patients with germline BRCA-mutated metastatic adenocarcinoma of the pancreas whose disease has not progressed on first-line platinum-based chemotherapy. Prostate Cancer: Olaparib is indicated as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and homologous recombination repair gene mutations (germline and/or somatic) who have progressed following a prior new hormonal agent.

Dosage and Administration: The recommended dose of Olaparib Tablets is 300 mg (two 150 mg tablets) taken orally twice daily, with or without food, for a total daily dose of 600 mg. The 100 mg tablet is available for dose reduction. Swallow tablets whole. Do not chew, crush, dissolve, or divide the tablet.

Contraindications: Hypersensitivity to the active substance or to any of the excipients used in the formulation.

Warnings & Precautions: Myelodysplastic Syndrome/Acute Myeloid Leukemia Overall, the incidence of Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) in patients treated with Olaparib Tablets monotherapy in clinical trials, including long-term follow-up, was < 6 months to > 2 years. Pneumonitis Pneumonitis, including fatal cases, occurred in <1% of patients treated with Olaparib Tablets. Embryo-Fetal Toxicity Olaparib Tablets can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals.

Drug Interactions: Anticancer Agents Clinical studies of Olaparib tablet in combination with other myelosuppressive anticancer agents, including DNA-damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity. Drugs That May Increase Olaparib Plasma Concentrations Avoid concomitant use of strong CYP3A inhibitors and moderate CYP3A inhibitors. Drugs That May Decrease Olaparib Plasma Concentrations Avoid concomitant use of strong CYP3A

inducers and moderate CYP3A4 inducers.

Pregnancy & Lactation: Pregnancy Based on findings in animals and its mechanism of action, Olaparib Tablets can cause fetal harm when administered to a pregnant woman. Lactation Because of the potential for serious adverse reactions in the breastfed infants from Olaparib Tablets, advise a lactating woman not to breastfeed during treatment with Olaparib Tablets and for one month after receiving the last dose.

Symptoms and Treatment of Overdosage: There is no specific treatment in the event of Olaparib overdose, and symptoms of overdose are not established. In the event of an overdose, physicians should follow general supportive measures and should treat the patient symptomatically.

Storage: Store below 30°C. Keep out of sight and reach of children.

Pack Size: 30 tablets are supplied in bottles.

Before prescribing, please consult full prescribing information available from Amneal Healthcare Private Limited (Formerly known as Amneal Biologics Private Limited) Regd. Office: 9th Floor, 901 to 905, Iscon Elegance, Circle P, S.G. Highway, Ahmedabad – 380015.

To be sold by retail on the prescription of an Oncologist only.