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Olarib Tablet

(Olaparib)

Film coated tablet 150mg

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۱۵۰ ملی گرام

Description:
Olarib (Olaparib) is Film coated tablet, for oral use.

Composition:
Each film coated tablet contains:
Olaparib.....150mg
As per Innovator's specification

CLINICAL PHARMACOLOGY

Mechanism of Action:
Olarib contains the active substance Olaparib. Olaparib is a type of cancer medicine called a PARP inhibitor (poly [adenosine diphosphate-ribose] polymerase inhibitor).
PARP inhibitors can destroy cancer cells that are not good at repairing DNA damage.

These specific cancer cells can be identified by:
• response to platinum chemotherapy, or
• looking for faulty DNA repair genes, such as BRCA (Breast Cancer) genes.

When Olarib is used in combination with abiraterone (an androgen receptor signaling inhibitor), the combination may help enhance anti-cancer effect in prostate cancer cells with or without faulty DNA repair genes (e.g., BRCA genes).

What Olarib is used for
Olarib is used for the treatment of
• a type of ovarian cancer (BRCA-mutated) that has responded to the first treatment with
standard platinum-based chemotherapy. – A test is used to find out whether you have BRCA-mutated ovarian cancer.
• ovarian cancer that has come back (recurred). It can be used after the cancer has responded to previous treatment with standard platinum-based chemotherapy.
• a type of ovarian cancer (HRD positive as defined by a BRCA mutation or genomic instability) that has responded to the first treatment with standard platinum-based chemotherapy and bevacizumab. Olarib is used together with bevacizumab.
• a type of breast cancer (BRCA-mutated, HER2-negative) when the cancer has not spread to other parts of the body and treatment is going to be given after surgery

(Treatment after surgery is called adjuvant therapy). You should have received chemotherapy medicines before or after surgery. If your cancer is hormone-receptor positive your doctor may also prescribe hormonal treatment. – A test is used to find out whether you have BRCA-mutated breast cancer.
• a type of breast cancer (BRCA-mutated, HER2-negative) which has spread beyond the original tumor. You should have received chemotherapy medicines either before or after your cancer has spread. – A test is used to find out whether you have BRCA-mutated breast cancer.
• a type of pancreatic cancer (BRCA-mutated) that has responded to the first treatment with standard platinum-based chemotherapy. – A test is used to find out whether you have BRCA-mutated pancreatic cancer.
• a type of prostate cancer (BRCA-mutated) which has spread beyond the original tumor and no longer responds to medical or surgical treatment to lower testosterone.
You should have received certain hormonal treatments, such as enzalutamide or abiraterone acetate. – A test is used to find out whether you have BRCA-mutated prostate cancer.
• a type of prostate cancer that has spread to other parts of the body (metastatic) beyond the original tumor and no longer responds to a medical or surgical treatment that lowers testosterone. Olarib is used in combination with another anti-cancer medicine called abiraterone, together with the steroid medicine, prednisone or prednisolone.
• a type of uterine cancer (MMR-proficient endometrial cancer) that has spread beyond the original tumor or come back (recurred). Olarib is used together with durvalumab if the cancer has not progressed after initial treatment with chemotherapy (carboplatin and paclitaxel) in combination with durvalumab. – A test is used to find out whether you have MMR-proficient endometrial cancer.

When Olarib is given in combination with other anti-cancer medicines it is important that you also read the package leaflets of these other medicines. If you have any questions about these medicines, ask your doctor.

PHARMACOKINETICS

Absorption
Following oral administration of Olaparib via the tablet formulation (2 x 150 mg), absorption is rapid with median peak plasma concentrations typically achieved 1.5 hours after dosing. Co-administration with food slowed the rate (tmax delayed by 2.5 hours and Cmax reduced by approximately 21%) but did not significantly affect the extent of absorption of Olaparib (AUC increased 8%). Consequently, Olarib may be taken without regard to food.
Distribution
The in vitro plasma protein binding is approximately 82% at 10 µg/mL which is approximately Cmax.
In vitro, human plasma protein binding of Olaparib was dose-dependent; the fraction bound was approximately 91% at 1 µg/mL, reducing to 82% at 10 µg/mL and to 70% at 40 µg/milk in solutions of purified proteins, the Olaparib fraction bound to albumin was approximately 56%, which was independent of Olaparib concentrations. Using the same assay, the fraction bound to alpha-1 acid glycoprotein was 29% at 10 µg/mL with a trend of decreased binding at higher concentrations.

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Metabolism
In vitro, CYP3A4/5 were shown to be the enzymes primarily responsible for the metabolism of Olaparib. Following oral dosing of 14C-olaparib to female patients, unchanged Olaparib accounted for the majority of the circulating radioactivity in plasma (70%) and was the major component found in both urine and feces (15% and 6% of the dose, respectively). The metabolism of Olaparib is extensive. The majority of the metabolism was attributable to oxidation reactions with a number of the components produced undergoing subsequent glucuronide or sulfate conjugation. Up to 20, 37 and 20 metabolites were detected in plasma, urine and feces, respectively, the majority of them representing < 1% of the dosed material. A ring-opened piperazin-3-ol moiety, and two mono-oxygenated metabolites (each ~10%) were the major circulating components, with one of the mono-oxygenated metabolites also being the major metabolite in the excreta (6% and 5% of the urinary and fecal radioactivity, respectively).
In vitro, Olaparib produced little/no inhibition of UGT1A4, UGT1A9, UGT2B7, or CYPs 1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6 or 2E1 and is not expected to be a clinically significant time dependent inhibitor of any of these CYP enzymes. Olaparib inhibited UGT1A1 in vitro, however, PBPK simulations suggest this is not of clinical importance. In vitro, Olaparib is a substrate of the efflux transporter P-gp, however, this is unlikely to be of clinical significance.
In vitro, data also show that Olaparib is not a substrate for OATP1B1, OATP1B3, OCT1, BCRP or MRP2 and is not an inhibitor of OATP1B3, OAT1 or MRP2
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Excretion
Following a single dose of 14C-olaparib, ~86% of the dosed radioactivity was recovered within a 7-day collection period, ~44% via the urine and ~42% via the feces. Majority of the material was excreted as metabolites.

THERAPEUTIC INDICATIONS

Ovarian cancer
Olarib is indicated as monotherapy for the:
• maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.
• maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.
Olarib in combination with bevacizumab is indicated for the:
• maintenance treatment of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a BRCA1/2 mutation and/or genomic instability.

Breast cancer
Olarib is indicated as:
• monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germline BRCA1/2-mutations who have HER2-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy.

• monotherapy for the treatment of adult patients with germline BRCA1/2 mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxeme in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments (5.1). Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy.

Adenocarcinoma of the pancreas
Olarib is indicated as monotherapy for the maintenance treatment of adult patients with germline BRCA1/2-mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen.

Prostate cancer
Olarib is indicated:
• as monotherapy for the treatment of adult patients with metastatic castration resistant prostate cancer (mCRPC) and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent.
• in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with mCRPC in whom chemotherapy is not clinically indicated.

Endometrial cancer
Olarib in combination with durvalumab is indicated for the maintenance treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair proficient (pMMR) whose disease has not progressed on first-line treatment with durvalumab in combination with carboplatin and paclitaxel.

DOSAGE & ADMINISTRATION
Olarib is available as 100 mg and 150 mg tablets.
The recommended dose of Olarib in monotherapy or in combination with other agents is 300 mg (two 150 mg tablets) taken twice daily, equivalent to a total daily dose of 600 mg. The 100 mg tablet is available for dose reduction.

Olarib monotherapy
Patients with platinum-sensitive relapsed (PSR) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy should start treatment with Olarib no later than 8 weeks after completion of their final dose of the platinum-containing regimen.

Olarib in combination with bevacizumab
When Olarib is used in combination with bevacizumab for the first-line maintenance treatment of high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer following completion of first-line platinum-based therapy with bevacizumab, the dose of bevacizumab is 15 mg/kg once every 3 weeks. Please refer to the full product information for bevacizumab.

Olarib in combination with endocrine therapy
Please refer to the full product information of the endocrine therapy combination

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partner(s) (aromatase inhibitor/anti-estrogen agent and/or LHRH) for the recommended posology.

Olarib in combination with abiraterone and prednisone or prednisolone
When Olarib is used in combination with abiraterone for the treatment of patients with mCRPC, the dose of abiraterone is 1000 mg orally once daily (5.1).
Abiraterone should be given with prednisone or prednisolone 5 mg orally twice daily.

Please refer to the full product information for abiraterone.

Olarib in combination with durvalumab
When Olarib is used in combination with durvalumab for the maintenance treatment of patients with MMR-Proficient (pMMR) primary advanced or recurrent endometrial cancer whose disease has not progressed on first-line treatment with durvalumab in combination with carboplatin and paclitaxel, the dose of durvalumab is
1500 mg every 4 weeks (5.1). Please refer to the full product information for durvalumab.

METHOD OF ADMINISTRATION
Oral

ADVERSE REACTIONS
Side effects reported in clinical studies with patients receiving Olarib alone:
Very common (may affect more than 1 in 10 people)
• feeling short of breath, feeling very tired, pale skin or fast heart beat – these may be symptoms of a decrease in the number of red blood cells (anemia). Uncommon (may affect up to 1 in 100 people)
• allergic reactions (e.g., hives, difficulty breathing or swallowing, dizziness which are signs
and symptoms of hypersensitivity reactions).
• itchy rash or swollen, reddened skin (dermatitis).
• serious problems with bone marrow (myelodysplastic syndrome or acute myeloid leukemia).
Other side effects include
Very common (may affect more than 1 in 10 people)
• feeling sick (nausea)
• being sick (vomiting)
• feeling tired or weak (fatigue)
• indigestion or heartburn (dyspepsia)
• loss of appetite
• headache
• changes in taste of foods (dysgeusia)
• feeling dizzy
• cough
• shortness of breath (dyspnea)
• diarrhea - if it gets severe, tell your doctor straight away

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients.
Breast-feeding during treatment and 1 month after the last dose.

Overdose:
In OLARIB clinical trials a limited number of patients were treated with daily doses of up to 240 mg without dose limiting toxicities. In these studies, patients who were treated with OLARIB daily doses of 160 mg and 240 mg experienced an increase in the frequency and severity of a number of typical EGFR TKI-induced AEs (primarily diarrhea and skin rash) compared to the 80 mg dose. There is limited experience with accidental overdoses in humans. All cases were isolated incidents of patients taking an additional daily dose of OLARIB in error, without any resulting clinical consequences.
There is no specific treatment in the event of OLARIB overdose. In case of suspected overdose, OLARIB should be withheld and symptomatic treatment initiated.

WARNINGS AND PRECAUTIONS
Talk to your doctor, pharmacist or nurse before or during treatment with Olarib
• if you have low blood cell counts on testing. These may be low counts for red or white blood cells, or low platelet counts. 4 for more information about these side effects, including the signs and symptoms you need to look out for (for example, fever or infection, bruising or bleeding). Rarely, these may be a sign of more serious problems with the bone marrow such as 'myelodysplastic syndrome' (MDS) or 'acute myeloid leukemia' (AML). When Olarib is used in combination with another anti-cancer medicine (durvalumab), a low blood cell count could be a sign of 'pure red cell aplasia' (PRCA), a condition in which no red blood cells are produced, or 'auto-immune hemolytic anemia' (AIHA), an excessive breakdown of red blood cells.
• if you experience any new or worsening symptoms of shortness of breath, coughing or wheezing. A small number of patients treated with Olarib reported inflammation of the lungs (pneumonitis). Pneumonitis is a serious condition that can often require hospital treatment.If you take more Olarib than your normal dose, contact your doctor or the nearest hospital straight away. If you forget to take Olarib, take your next normal dose at its scheduled time. Do not take a
double dose (two doses at the same time) to make up for a forgotten dose.

DRUG INTERACTIONS

Pharmacodynamic interactions
Clinical studies of Olaparib in combination with other anticancer medicinal products,
including DNA damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity. The recommended Olarib monotherapy dose is not suitable for combination with myelosuppressive anticancer medicinal products.
Combination of Olaparib with vaccines or immunosuppressant agents has not been studied. Therefore, caution should be taken if these medicinal products are co-administered with Olarib and patients should be closely monitored.
Pharmacokinetic interactions.
Effect of other medicinal products on Olaparib CYP3A4/5 are the isozymes predominantly responsible for the metabolic clearance of Olaparib.

A clinical study to evaluate the impact of itraconazole, a known CYP3A inhibitor, has shown that co-administration with Olaparib increased mean Olaparib Cmax by 42% (90% CI: 33-52%) and mean AUC by 170% (90% CI: 144-197%). Therefore, known strong (e.g., itraconazole, telithromycin, clarithromycin, protease inhibitors

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boosted with ritonavir or cobicistat, boceprevir, telaprevir) or moderate (e.g., erythromycin, diltiazem, fluconazole, verapamil) inhibitors of this isozyme are not recommended with Olarib (4.4). If strong or moderate CYP3A inhibitors must be co-administered, the dose of Olarib should be reduced. The recommended Olarib dose reduction is to 100 mg taken twice daily (equivalent to a total daily dose of 200 mg) with a strong CYP3A inhibitor or 150 mg taken twice daily (Equivalent to a total daily dose of 300 mg) with a moderate CYP3A inhibitor (see sections 4.2 and 4.4). It is also not recommended to consume grapefruit juice while on Olarib therapy as it is a CYP3A inhibitor.
A clinical study to evaluate the impact of rifampicin, a known CYP3A inducer, has shown that co-administration with Olaparib decreased Olaparib mean Cmax by 71% (90% CI: 76-67%) and mean AUC by 87% (90% CI: 89-84%). Therefore, known strong inducers of this isozyme (e.g., phenytoin, rifampicin, rifapentine, carbamazepine, nevirapine, phenobarbital and St John's Wort) are not recommended with Olarib, as it is possible that the efficacy of Olarib could be substantially reduced. The magnitude of the effect of moderate to strong inducers (e.g., efavirenz, rifabutin) on Olaparib exposure is not established, therefore the co-administration of Olarib with these medicinal products is also not recommended. Effect of Olaparib on other medicinal products Olaparib inhibits CYP3A4 in vitro and is predicted to be a mild CYP3A inhibitor in vivo. Therefore, caution should be exercised when sensitive CYP3A substrates or substrates with a narrow therapeutic margin (e.g., simvastatin, tiapride, cyclosporine, ergot alkaloids, fentanyl, pimozide, sirolimus, tacrolimus and quetiapine) are combined with Olaparib. Appropriate clinical monitoring is recommended for patients receiving CYP3A substrates with a narrow therapeutic margin concomitantly with Olaparib. Induction of CYP1A2, 2B6 and 3A4 has been shown in vitro with CYP2B6 being most likely to be induced to a clinically relevant extent. The potential for Olaparib to induce CYP2C9, CYP2C19 and P-gp can also not be excluded. Therefore, Olaparib upon co-administration may reduce the exposure to substrates of these metabolic enzymes and transport protein. The efficacy of some hormonal contraceptives may be reduced if co-administered with Olaparib. In vitro, Olaparib inhibits the efflux transporter P-gp (IC50 = 76 µM), therefore it cannot be excluded that Olaparib may cause clinically relevant drug interactions with substrates of P-gp (e.g., simvastatin, pravastatin, dabigatran, digoxin and colchicine). Appropriate clinical monitoring is recommended for patients receiving this type of medicinal product concomitantly. In vitro, Olaparib has been shown to be an inhibitor of BCRP, OATP1B1, OCT1, OCT2, OAT3, MATE1 and MATE2K. It cannot be excluded that Olaparib may increase the exposure to substrates of BCRP (e.g., methotrexate, rosuvastatin), OATP1B1 (e.g., bosentan, glibenclamide, repaglinide, statins and valsartan), OCT1 (e.g., metformin), OCT2 (e.g., serum creatinine), OAT3 (e.g., furosemide and methotrexate), MATE1 (e.g., metformin) and MATE2K (e.g., metformin). In particular, caution should be exercised if Olaparib is administered in combination with any statin.

Combination with anastrozole, letrozole and tamoxifen
A clinical study has been performed to assess the combination of Olaparib with anastrozole, letrozole or tamoxifen. No clinically relevant interactions were observed.

HOW SUPPLIED
Olarib (Olaparib) Film Coated Tablet 150mg available in blister pack of 6x10's & 12x10's

Instructions: Store at 25°C (Excursions permitted between 15°C to 30°C).
Protect from sunlight & moisture.
Keep out of the reach of children.
To be dispensed on the prescription of a registered medical practitioner only.

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات : دوا کو ۲۵ ڈگری سینٹی گریڈ درجہ حرارت پر رکھیں
(درجہ حرارت کی حد ۱۵ سے ۳۰ ڈگری سینٹی گریڈ ہے)۔
دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
Kaizen Pharmaceuticals (Pvt) Ltd.,
E-127, E-128 & E-129, North Western Industrial Zone,
Port Qasim Authority, Karachi-75020, Pakistan.

Art no: 1390

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Reference of Olaparib;

Quick top-line (with primary citations)

- **Olaparib** is a PARP inhibitor with multiple regulatory approvals (ovarian, breast, pancreatic, prostate) based on randomized trials showing improvements in progression-free survival and, in some settings, overall survival. New England Journal of Medicine+3New England Journal of Medicine+3New England Journal of Medicine+3

Regulatory / Prescribing information

- Lynparza (olaparib) — US Prescribing Information (FDA). (Full label and updates). New England Journal of Medicine
- EMA product information / EPAR for Lynparza. (European approval documents). New England Journal of Medicine

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Pivotal randomized trials (complete references)

Ovarian cancer — first-line and relapsed/maintenance

1. Moore K, Colombo N, Scotte F, et al. *Maintenance Olaparib in Patients with Newly Diagnosed Advanced Ovarian Cancer and a BRCA Mutation (SOLO-1).* N Engl J Med. 2018;379:2495–2505. doi:10.1056/NEJMoa1810858. New England Journal of Medicine+1
2. Pujade-Lauraine E, Ledermann JA, Selle F, et al. *Olaparib tablets as maintenance therapy in patients with platinum-sensitive, relapsed ovarian cancer and a BRCA1/2 mutation (SOLO2/ENGOT-Ov21): a double-blind, randomized, placebo-controlled, phase 3 trial.* Lancet Oncol. 2017;18(9):1274–1284. doi:10.1016/S1470-2045(17)30469-2. The Lancet+1
3. Ledermann J, Harter P, Gourley C, et al. *Olaparib maintenance therapy in platinum-sensitive relapsed serous ovarian cancer (Study 19): randomized phase II.* N Engl J Med. 2012;366:1382–1392. doi:10.1056/NEJMoa1105535. (Study 19 — early pivotal maintenance trial). New England Journal of Medicine+1
4. Ray-Coquard I, Pautier P, Pignata S, et al. *Olaparib plus bevacizumab as first-line maintenance in ovarian cancer (PAOLA-1).* N Engl J Med. 2019;381:2416–2428. doi:10.1056/NEJMoa1911361. New England Journal of Medicine

Breast cancer

5. Robson M, Im S-A, Senkus E, et al. *Olaparib for Metastatic Breast Cancer in Patients with a Germline BRCA Mutation (OlympiAD).* N Engl J Med. 2017;377:523–533. doi:10.1056/NEJMoa1706450. New England Journal of Medicine

6. Tutt ANJ, Garber JE, Kaufman B, et al. *Adjuvant Olaparib for Patients with BRCA1- or BRCA2-mutated High-Risk HER2-Negative Early Breast Cancer (OlympiA).* N Engl J Med. 2021;384:2394–2405. doi:10.1056/NEJMoa2105215. New England Journal of Medicine+1

Pancreatic cancer

7. Golan T, Hammel P, Reni M, et al. *Maintenance Olaparib for Germline BRCA-mutated Metastatic Pancreatic Cancer (POLO).* N Engl J Med. 2019;381:317–327. doi:10.1056/NEJMoa1903387. New England Journal of Medicine+1

Prostate cancer (mCRPC)

8. de Bono J, Mateo J, Fizazi K, et al. *Olaparib for Metastatic Castration-Resistant Prostate Cancer (PROfound).* N Engl J Med. 2020;382:2091–2102. doi:10.1056/NEJMoa1911440. New England Journal of Medicine+1

9. Hussain M, Mateo J, Fizazi K, et al. *Survival with Olaparib in Metastatic Castration-Resistant Prostate Cancer.* N Engl J Med. 2020;382:2091–2102 (OS/subgroup analyses and follow-up publications). New England Journal of Medicine

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Key Phase I/II, combination & mechanistic studies

10. Bryant HE, Schultz N, Thomas HD, et al. *Specific killing of BRCA2-deficient tumours with inhibitors of poly(ADP-ribose) polymerase.* Nature. 2005;434:913–917. (Foundational preclinical work on PARP inhibition synthetic lethality — background for olaparib development).

11. Fong PC, Boss DS, Yap TA, et al. *Inhibition of poly(ADP-ribose) polymerase in tumors from BRCA mutation carriers.* N Engl J Med. 2009;361:123–134. (Early clinical activity).

12. Various Phase I/II combination studies: olaparib + chemotherapy, olaparib + anti-angiogenic agents (PAOLA-1), olaparib + immune checkpoint inhibitors — see individual trial publications and ClinicalTrials.gov listings for details. New England Journal of Medicine

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Safety / PK / long-term follow-up studies

13. DiSilvestro P, et al. *Overall survival with maintenance olaparib at a 7-year follow-up in patients with newly diagnosed advanced ovarian cancer and a BRCA mutation (SOLO1 long-term).* J Clin Oncol. 2023; (long-term follow-up). PubMed

14. Korach J, et al. *Long-term tolerability of olaparib tablets as maintenance therapy (SOLO2).* Ann Oncol. 2018; (safety / tolerability data). annalsofoncology.org

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Important reviews, meta-analyses & guideline papers

15. Ledermann JA. *Olaparib as maintenance treatment for patients with ovarian cancer: review of SOLO trials and Study 19.* Ther Adv Med Oncol. 2019;11:1758835919849753. SAGE Journals

16. Mateo J, Ashworth A, Lord CJ. *A decade of PARP inhibitors in cancer therapy.* Nat Rev Cancer. 2023; (comprehensive review of PARP inhibitor history, mechanisms, resistance).

17. ASCO/ESMO practice guidelines and consensus statements referencing olaparib in ovarian, breast, pancreatic, and prostate settings — consult the latest guideline documents for specific recommendation lines and levels of evidence. New England Journal of Medicine

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Selected trial identifiers (useful to find full protocols/data)

- NCT00753545 — Study 19 (olaparib maintenance, relapsed ovarian). PubMed
- NCT01874353 — SOLO2 / ENGOT-Ov21. UCL Discovery
- NCT01844986 / NCT01945775 — SOLO-1 related trial identifiers (check ClinicalTrials.gov for substudies). New England Journal of Medicine
- NCT02000622 — OlympiAD (olaparib in metastatic BRCA-mutated breast cancer). New England Journal of Medicine
- NCT02184195 — POLO (pancreatic maintenance). PubMed
- NCT02987543 / PROfound registry details in ClinicalTrials.gov for prostate studies. PubMed

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Where to download the full PDFs and authoritative sources

- **NEJM** site: SOLO-1 (Moore 2018), OlympiAD (Robson 2017), PROfound (de Bono 2020), POLO (Golan 2019). New England Journal of Medicine+3New England Journal of Medicine+3New England Journal of Medicine+3
- **Lancet Oncology**: SOLO2 (Pujade-Lauraine 2017). The Lancet
- **PubMed / PubMed Central** for indexed abstracts and links to full text. PubMed+1

Helpful curated reading order (if you want to study olaparib quickly)

1. **Preclinical / mechanism background:** Bryant et al., Nature (2005); Fong et al., NEJM (2009).
2. **Early clinical signal and Study 19 (maintenance in relapsed ovarian):** Ledermann et al., NEJM 2012. New England Journal of Medicine
3. **Pivotal ovarian trials:** SOLO2 (Lancet Oncol 2017) → SOLO1 (NEJM 2018) → PAOLA-1 (NEJM 2019). The Lancet+2New England Journal of Medicine+2
4. **Breast cancer:** OlympiAD (NEJM 2017) and OlympiA (NEJM 2021). New England Journal of Medicine+1
5. **Pancreas & prostate pivotal trials:** POLO (NEJM 2019) and PROfound (NEJM 2020). New England Journal of Medicine+1
6. **Long-term follow-up & safety:** SOLO1/7-year follow-up (JCO/ASCO abstracts and publications). PubMed