



Package leaflet: Information for the patient

Olieni 100 mg/150 mg film-coated tablets

olaparib

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Olieni is and what it is used for
2. What you need to know before you take Olieni
3. How to take Olieni
4. Possible side effects
5. How to store Olieni
6. Contents of the pack and other information

1. What Olieni is and what it is used for

What Olieni is and how it works

Olieni film-coated tablets contain the active substance Olaparib. Olaparib is a type of cancer medicine called a PARP (poly [adenosine diphosphate-ribose] polymerase) inhibitor.

In patients with mutations (changes) in certain genes called BRCA (breast cancer gene), who are at risk of developing some forms of cancer, PARP inhibitors are able to trigger the death of cancer cells by blocking an enzyme that helps repair DNA.

What Olieni is used for

Olieni is a prescription medicine used for:

- the maintenance treatment of adults with ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, when the cancer has come back. Olieni is used after the cancer has responded to treatment with platinum-based chemotherapy.
- the treatment of adults who have a certain type of abnormal inherited BRCA gene advanced ovarian cancer, and have received treatment with 3 or more prior types of chemotherapy medicines. Your healthcare provider will perform a test to make sure that Olieni is right for you. It is not known if Olieni is safe and effective in children.

2. What you need to know before you take Olieni

Do not take Olieni:

- if you are allergic to Olaparib or any of the other ingredients of this medicine (listed in section 6).

Do not take Olieni if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist, or nurse before taking Olieni.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before or during treatment with Olieni:

If you have low blood-cell counts on testing. These may be low red blood-cell count (anaemia), low white blood-cell count (neutropenia), or low blood-platelet count (thrombocytopenia). See section 4 for more information about these side effects. This includes the signs and symptoms you need to look out for (fever or infection, bruising or bleeding).

Rarely, these may be a sign of more serious problem with the bone marrow such as 'myelodysplastic syndrome' (MDS) or 'acute myeloid leukaemia' (AML). Your doctor may want to test your bone marrow to check for these problems.

If you experience any new or worsening symptoms of shortness of breath, coughing, or wheezing. A small number of patients treated with Olieni reported inflammation of the lungs (pneumonitis). Pneumonitis is a serious condition that can often require hospital treatment.

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse.

Tests and checks

Your doctor will check your blood before and during treatment with Olieni.

You will have a blood test:

- before treatment
- every month for the first year of treatment
- at regular intervals decided by your doctor after the first year of treatment.

If your blood count falls to a low level, it may be necessary to have a blood transfusion (where you are given new blood or blood-based products from a donor).

Other medicines and Olieni

Tell your doctor, pharmacist, or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Olieni can affect the way some other medicines work. Also some other medicines can affect the way Olieni works.

Do not take Olieni if you are taking any other anticancer medicines. Tell your doctor, pharmacist, or nurse if you are planning on receiving a vaccine or a medicine that suppresses the immune system, as you may need to be closely monitored.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- itraconazole, fluconazole -- used for fungal infections
- telithromycin, clarithromycin, erythromycin - used for bacterial infections
- protease inhibitors boosted with ritonavir or cobicistat, boceprevir, telaprevir, nevirapine, efavirenz - used for viral infections, including HIV
- rifampicin, rifapentine, rifabutin - used for bacterial infections, including tuberculosis (TB)
- phenytoin, carbamazepine, phenobarbital - used as a sedative or to treat fits (seizures) and epilepsy
- St John's Wort (Hypericum perforatum) - a herbal medicine used mainly for depression
- Digoxin, diltiazem, furosemide, verapamil, valsartan - used to treat heart conditions or high blood pressure
- Bosentan - used to treat pulmonary artery hypertension
- Statins, for example simvastatin, pravastatin - used to lower blood cholesterol levels
- Dabigatran - used to thin the blood
- Glibenclamide, metformin, repaglinide - used to treat diabetes
- Ergot alkaloids - used to treat migraines and headaches
- Fentanyl - used to treat cancer pain
- Pimozide - used to treat schizophrenia
- Quetiapine - used to treat schizophrenia and bipolar disorder
- Cisapride - used to treat stomach problems
- Colchicine - used to treat gout
- Cyclosporine, sirolimus, tacrolimus - used to suppress the immune system
- Methotrexate - used to treat cancer, rheumatoid arthritis and psoriasis

Olieni with drink

Do not drink grapefruit juice throughout the whole period of time you are taking Olieni. It can affect the way the medicine works.

Pregnancy and breast-feeding

- You should not take Olieni if you are pregnant or might become pregnant. This is because it may harm an unborn baby.
- You should avoid becoming pregnant while taking this medicine. You should use effective methods of contraception while taking this medicine and for 1 month after receiving the last dose of Olieni. It is not known whether Olieni may affect the effectiveness of some oral contraceptives. Please tell your doctor if you are taking an oral contraceptive, as your doctor may recommend the addition of a non-hormonal contraceptive method.
- You should have a pregnancy test before starting Olieni and at regular times during treatment and 1 month after receiving the last dose of Olieni. If you become pregnant during this time, you must talk to your doctor straight away.
- It is not known whether Olieni passes into breast milk. Do not breast-feed if you are taking Olieni and for one month after receiving the last dose of Olieni. If you are planning to breast-feed, tell your doctor.

Driving and using machines

Olieni may influence your ability to drive and use machines. If you feel dizzy, weak, or tired while taking Olieni, do not drive or use tools or machines.

3. How to take Olieni

Always take this medicine exactly as your doctor, pharmacist, or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

How much to take

- The recommended dose of Olieni film-coated 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. Continue treatment until disease progression or unacceptable toxicity. It is important that you take the total recommended daily dose and continue to do so as instructed by your doctor, pharmacist, or nurse.

How to take

- Take Olieni tablets exactly as your healthcare provider tells you.
- Your healthcare provider may temporarily stop treatment with Olieni or change your dose of Olieni if you experience side effects.
- Olieni comes as tablets and capsules. Olieni tablets and capsules are not the same. If your healthcare provider prescribes Olieni tablets for you, do not take Olieni capsules. Do not take more than 4 Olieni tablets in 1 day. If you have any questions about Olieni, talk to your healthcare provider or pharmacist.
- Take Olieni by mouth 2 times a day.

- Each dose should be taken about 12 hours apart.
- Swallow Olieni tablets whole. Do not chew, crush, dissolve, or divide the tablets.
- Take Olieni with or without food.
- If you miss a dose of Olieni, take your next dose at your usual scheduled time. Do not take an extra dose to make up for a missed dose.
- If you take too much Olieni, call your healthcare provider or go to the nearest hospital emergency room right away. If you experience side effects, your doctor may tell you to take Olieni at a lower dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be.

Your doctor may also prescribe other medicines to help control your side effects.

Tell your doctor straight away if you notice any of the following side effects – you may need urgent medical treatment:

Very common (may affect more than 1 in 10 people):

- fever or infection – these may be signs of a low white blood cell count (neutropaenia or lymphopaenia).
- being short of breath, feeling very tired, having pale skin, or fast heart beat - these may be signs of a low red blood cell count (anaemia).

Common (may affect up to 1 in 10 people):

- bruising or bleeding for longer than usual if you hurt yourself - these may be signs of a low blood platelet count (thrombocytopenia).

Tell your doctor straight away if you notice any of the side effects listed above.

Other side effects include:

Very common

- headache
- feeling dizzy
- loss of appetite
- feeling tired or weak
- feeling sick (nausea)
- being sick (vomiting)
- changes in the way food tastes
- indigestion or heartburn (dyspepsia)
- diarrhoea. If it gets severe, tell your doctor straight away
- increase in blood creatinine levels seen from a laboratory test showing how well your kidneys are working
- blood test showing increase of red blood cell size.

Common

- sore mouth (stomatitis)
- pain in the stomach area under the ribs.

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. Your doctor may prescribe a medicine to treat your symptoms such as nausea, vomiting, diarrhoea, and dyspepsia.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Olieni

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP.

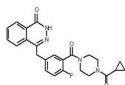
Do not store above 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Olieni contains

The active substance is Olaparib. It is an inhibitor of the mammalian polyadenosine 5'-diphosphoribose polymerase (PARP) enzyme. The chemical name is 4-[[3-[[4-(cyclopropylcarbonyl)piperazin-1-yl]carbonyl]-4-fluorophenyl)methyl]phthalazin-1(2H)one and it has the following chemical structure:



The empirical molecular formula for Olieni is C₂₄H₂₃FN₄O₃ and the relative molecular mass is 434.46. Olaparib is a crystalline solid. Each film-coated tablet contains 100 mg or 150mg of Olaparib.

The other ingredients (excipients) are:

- The other ingredients in the tablet core are copovidone, mannitol, colloidal silicon dioxide and sodium stearyl fumarate.

The tablet coating consists of hypromellose, polyethylene glycol 400, titanium dioxide, ferric oxide yellow and ferrousferrous oxide (150 mg tablet only).

What Olieni looks like and contents of the pack

- The Olieni 100 mg film-coated tablet is a yellow, oval film-coated tablet with "TLPH" engraved on one side.
- The Olieni 150 mg film-coated tablet is a green, oval film-coated tablet with "TLPH" engraved on one side.

Olieni is provided in HDPE plastic bottles containing 60 tablets. Not all pack sizes may be marketed.

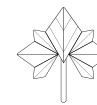
Marketing Authorisation Holder

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd
Rd13 South,31km,Ban Naphasuk,Saithany District
Vientiane
Lao PDR

Manufacturer

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd
Rd13 South,31km,Ban Naphasuk,Saithany District
Vientiane
Lao PDR

For any information about this medicine, please contact the local representative of the Marketing.



TLPH