



23 April 2019
EMA/107399/2018

Lynparza: warning that new tablets are used at different doses to the capsules

Risk of medication error if form and dosages not clearly specified in prescriptions

Healthcare professionals are being informed that the new tablet form of the cancer medicine Lynparza (olaparib) is used at different doses to the existing capsules. The new tablets are available in two strengths: 100 and 150 mg.

The usual dose for the new tablets is 300 mg twice daily while usual dose for the capsules is 400 mg twice daily. The lower doses for patients experiencing side effects are also not the same for the two forms (see table below). In most cases, patients will take fewer tablets than capsules.

Due to these differences, there is an increased risk the medicine will cause side effects or not work properly if patients incorrectly take one form in place of the other.

Prescribers should specify the form and dose of Lynparza on each prescription, and pharmacists should take care to dispense the correct form.

Healthcare professionals should also explain to patients switching from capsules to tablets (or vice-versa) that the doses in milligrams are different and the number of tablets to take will be different from the number of capsules.

Healthcare professionals in the EU will receive a letter with further information.

| How to prescribe Lynparza* | | |
|----------------------------|--|---|
| | <i>Capsules (50 mg)</i> | <i>Tablets (100 and 150 mg)</i> |
| Usual dose | 400 mg (8 capsules) twice daily | 300 mg (2 × 150 mg tablets) twice daily |
| Initial dose reduction** | 200 mg (4 capsules) twice daily | 250 mg (1 × 150 mg + 1 × 100 mg tablets) twice daily |
| Further dose reduction | 100 mg (2 capsules) twice daily | 200 mg (2 × 100 mg tablets) twice daily |

* Capsules are taken without food; tablets can be taken with or without food.

** Doses may be reduced for patients experiencing side effects (see Product Information for more details).



Information for patients

- Lynparza is now available in two different forms: tablets (100 and 150 mg) and capsules (50 mg).
- The doses are different for the tablets and capsules, and the number of tablets to take will be different from the number of capsules (see table above). Another difference is that the capsules must be taken without food while tablets can be taken with or without food.
- Always take your medicine as your doctor has told you to, paying attention to the dose, particularly if you have switched from one form to another.
- If you have switched treatment, you should only take your new medicines. You should return any old medicines you have to a pharmacist.
- Contact your doctor or pharmacist if you have any questions about your treatment.

Further information for healthcare professionals

- Do not substitute tablets for capsules (or vice versa) on a milligram-to-milligram basis. This is because of differences in bioavailability between the two forms.
- Substituting one form for another on a milligram-to-milligram basis can result in overdosing (leading to side effects) or underdosing (leading to lack of effect).
- If you switch a patient from one form to another, instruct them to only use the new medicines and to return any old medicines.
- Specify the form and dosage of Lynparza on each prescription. Pharmacists should take care to dispense the correct form.
- Instruct patients on the correct dose of their tablets or capsules. For any patients switching from capsules to tablets (or vice-versa), explain that the doses in milligrams are different and the number of tablets to take will be different to the number of capsules.
- The indications for Lynparza tablets and capsules are as follows:
 - Lynparza 100 mg and 150 mg tablets
Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.
 - Lynparza 50 mg capsules
Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.

More about the medicine

Lynparza is a cancer medicine used for epithelial cancer of the ovary, including cancers of the fallopian tubes (part of the female reproductive system that connect the ovaries to the uterus) and of the peritoneum (the membrane lining the abdomen).

The active substance, olaparib, blocks the action of PARP, enzymes that help to repair damaged DNA in cells. While normal cells have alternative mechanisms for repairing DNA, these mechanisms do not work properly in cancer cells. The blocking of PARP therefore leads to death of the cancer cells.

More information on Lynparza is available on the [medicine's dedicated webpage](#).