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Dear Healthcare Professional Communication

8th May 2018

LYNPARZA ▼ (Olaparib): Risk of medication errors with new pharmaceutical form

Dear Healthcare Professional,

AstraZeneca in agreement with the European Medicines Agency and MHRA would like to inform you of the following:

Summary

- A tablet formulation of LYNPARZA (olaparib) was approved by the European Commission on the 8th May 2018.
- LYNPARZA capsules and tablets are not to be substituted on a milligram-to-milligram basis due to differences in dosing and bioavailability of each formulation.
- To avoid medication errors, prescribers should specify the formulation and dosage of LYNPARZA on each prescription and pharmacists should ensure that the correct formulation and dose is dispensed to patients.
- Instruct patients on the correct dose they should take for their capsules or tablets. For any patients switching from capsules to tablets (or vice-versa), explain how the doses in milligrams for the two forms are different.

Background on the safety concern

LYNPARZA (olaparib) **tablet** formulation is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade

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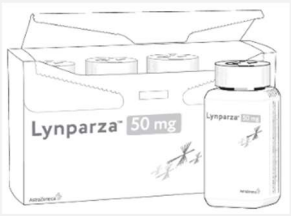
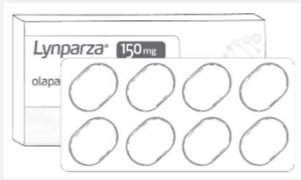
epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

LYNPARZA (olaparib) **capsule** formulation is indicated as 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.

The posology for tablets and capsules is different (see image below) and the two formulations should not be substituted on a milligram-to-milligram basis; there is a risk of overdose and increased adverse events if the capsule posology is used for the tablets or lack of efficacy if the tablet posology is used for the capsules.

Strength, Dosage Formulation and Packaging	Capsules 50 mg 	Tablets 150 mg 	Tablets 100 mg 
Recommended Dosage	400 mg twice daily Morning 8 x  Evening 8 x  Total Daily Dosage: 800mg	300 mg twice daily Morning 2 x  Evening 2 x  Total Daily Dosage: 600mg	**Only to be used for tablet dose reductions** 
Dose adjustment (e.g. for adverse reactions)	Dose reductions are achieved using fewer 50mg capsules **Initial reduced dosage:** 200 mg (4 x 50mg capsules) twice daily (total daily dosage: 400 mg) **For further reductions use:** 100 mg (2 x 50mg capsules) twice daily (total daily dosage: 200 mg)	Dose reductions are achieved using 100mg tablets (refer to next panel)	**Initial reduced dosage:** 250mg (1 x 150mg tablet and 1 x 100mg tablet) twice daily (total daily dosage: 500mg) **For further reductions use:** 200mg (2 x 100mg tablets) twice daily (total daily dosage: 400mg)

N.B. Images of the formulation are representations only and are not to scale.

The SmPCs, package leaflets and packaging for both formulations of LYNPARZA include information that the two formulations are not to be substituted on a milligram-to-milligram basis.

Call for reporting

LYNPARZA is subject to additional monitoring because it contains a new active substance.

Please report suspected adverse drug reactions (ADR's) to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼.

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name".

Company contact point

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Product Information

Full product information can be found via the eMC website:

https://www.medicines.org.uk/emc/

Yours sincerely,

Dr Cham Herath
Director of Healthcare and Medical Affairs UK