ASSOCIATED DRUG COMPANY LIMITED
TRIQ L-ESPORTATURI, MRIEHEL, BIRKIRKARA BKR 3000, MALTA
TEL: 2277 8000 FAX: 2277 8120

**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 the Medicines Authority 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 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.

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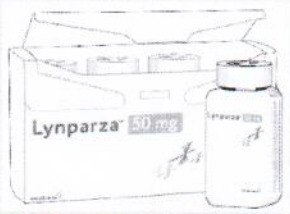
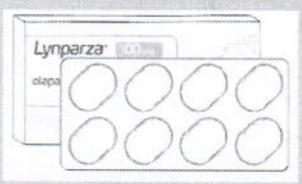
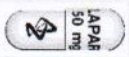
The posology for tablets and capsules is different (see image below) and the two formulations should not be substituted on a milligram-to-milligram basis; there is a risk of overdose and increased adverse events if the capsule posology is used for the tablets or lack of efficacy if the tablet posology 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<br>Morning: 8 x  <br>Evening: 8 x  <br>Total Daily Dosage: 800mg | 300 mg twice daily<br>Morning: 2 x  <br>Evening: 2 x  <br>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<br>**Initial reduced dosage:** 200 mg (4 x 50mg capsules) twice daily (total daily dosage: 400 mg)<br>**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)<br>**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.

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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.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt

Adverse Events should also be reported to Associated Drug Co. Ltd on 00356 22778115.

***Company contact point***

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Yours sincerely,

Alexia Farrugia

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