

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

26/11/2020

Dear Pharmacist,

As you may be aware from the recent DHPC communication a new TABLET formulation of olaparib is now being made available on the High Tech arrangements of the PCRS Community Drug Schemes. Olaparib CAPSULES have been available in Ireland since 2017.

The NCCP would like to draw your attention to some safety considerations around the use of this new pharmaceutical formulation of olaparib:

- The posology differs between the TABLETS and the CAPSULES formulations (as detailed in Figure 1 below).
- The SmPC's, package leaflets and packaging for both formulations of olaparib include information that the two formulations are not to be substituted on a milligram-to-milligram basis due to differences in bioavailability of each formulation. **There is no agreed conversion calculation.**
 - there is a risk of overdose and increased adverse events if the capsule formulation is used for the tablets or lack of efficacy if the tablet formulation is used for the capsules.
- The formulation and dosage of olaparib should be specified on each prescription and pharmacists are asked to ensure that the correct formulation and dose is dispensed to patients.
- Pharmacists should instruct patients on the correct dose they should take for their capsules or tablets.
- Pharmacists should explain how the doses in milligrams for the two forms are different when patients currently on treatment with capsules are transitioned to tablets.

Following from feedback from clinicians it is expected that patients currently on the capsules may be transitioned to the tablet formulation. The NCCP has requested clinicians not to transition patients until January 2021 as there is a limited supply of tablets currently available for patients who may be eligible to commence treatment. Separately, the NCCP understands that production of the capsule formulation of olaparib is expected to cease in December 2021.

The National Chemotherapy regimens for olaparib are available at this [link](#).

Additional SACT resources for community pharmacists available at this [link](#) in addition to the online course on Oral Anticancer Medicines available at <https://iiop.ie/>

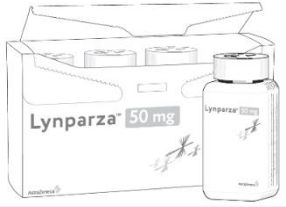

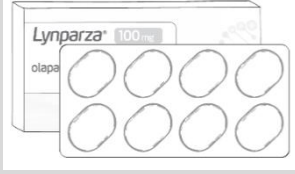

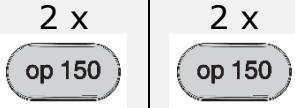

Any queries should be directed via email to the NCCP at oncologydrugs@cancercontrol.ie

Yours sincerely,



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Figure 1 Comparison of LYNPARZA (olaparib) Capsules and Tablet Formulations (courtesy of DHPC Communication Astra-Zeneca)

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

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