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March 2018

Reference: Recall of specific batches of Lynparza 50mg capsules

Dear Healthcare Professional

Class 3 medicines recall: Specific batches of Lynparza™▼(olaparib) 50mg capsules

AstraZeneca would like to inform you of an out of specification result for a specific batch of Lynparza (olaparib) 50mg capsules. This batch (NG327) is being recalled at the pharmacy level. As a precautionary measure we are also recalling additional batches outlined below.

About Lynparza Capsules

Lynparza 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.

About the recall

Assuring the supply of quality medicines to our patients is our number one priority.

Olaparib, the active ingredient in Lynparza capsules, can exist in two crystalline polymorphic forms, Form A and Form L. Form A is more soluble than Form L and is the preferred polymorphic form. During regular medicinal product monitoring, raised levels of Form L were detected in one batch of Lynparza 50mg capsules and exceeded the registered specification limit of 10%. AstraZeneca is therefore recalling this specific batch (NG327). Although the level of Form L has exceeded the registered specification limit, it is well below the 20% threshold considered to have a potential clinical impact;(reduction in efficacy due to lower solubility).

There is no safety risk to patients taking Lynparza capsules containing any level of polymorphic Form L.

As a precautionary measure, AstraZeneca is also recalling some additional batches that remain within the registered specification limit at this time, but have a higher risk of exceeding the 10% specification limit before the end of their shelf life.

This recall will not impact availability of Lynparza 50mg capsules to patients.

Affected batches for recall

Table 1: Drug product lot subject to out of specification result for polymorph L

Packed Lot Number	Expiry date
NG327	31/10/18

Table 2: Additional drug product lots recalled as precautionary measure

Packed Lot Number	Expiry date
NG143	30/11/2018
NK719	30/06/2018
NJ972	30/06/2018
NR730	31/07/2018
NK591	30/04/2018
NR497	30/04/2018

All other batches of Lynparza 50mg capsules are not impacted by this recall.

What you need to do

AstraZeneca is asking you to:

1. Stop dispensing the specific batches detailed in Table 1 & 2 immediately.
2. Return all remaining stock of these batches to your agent using the agent's approved process as soon as possible.
3. Complete the response slip to confirm either you are returning packs or that you do not have any stocks of the specific batches in Table 1 & 2 **within 5 days**.
4. Return the completed response slip using the pre-paid envelope provided or via email to supply.chain@astrazeneca.com.
   Email responses must include Lynparza in the Subject field & the responder's name and organisation in the body of the email.

Please do not return any stock directly to AstraZeneca

For more information

Please contact the Medical Information and Patient Safety team at AstraZeneca should you have any questions.

AstraZeneca Medical Information: 0800 783 0033

AstraZeneca Medical Information e-mail medical.informationuk@astrazeneca.com

Thank you for your help and apologies for any inconvenience this may cause.

Call for reporting

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

Yours sincerely

Cham Herath
Medical and Healthcare Affairs Director
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Hospital address
(as printed on the envelope)

RESPONSE SLIP

Please select one of the two options below, please return this reply card in the provided pre-paid envelope and post to AstraZeneca.

☐ I confirm I currently have stock from the affected batches as outlined above and will be returning this stock to my agent using the agent's approved process as soon as possible

☐ I confirm I have **no** stock from the affected batches

……..
Signature

……..
Print name