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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

ZEJULA (niraparib) 100mg film-coated tablets:
Repack of specific batches with the contemporaneous Patient Information Leaflet

Dear Healthcare professional,

Summary: GlaxoSmithKline (GSK) is repacking specific batches of ZEJULA (niraparib) 100mg film-coated tablets to ensure patient access to the latest Patient Information Leaflet (PIL).

This letter is intended to provide you, the healthcare professional only, with information about the arrangements concerning the Medicines and Healthcare products Regulatory Agency (MHRA) approval of GSK repacking specific batches of niraparib 100mg film-coated tablets, to include the latest PIL. The specific batch numbers, size and expiry dates are summarised in a table at the end of this letter. This letter must be removed from the clear sealable bag before the bag is given to the patient.

Please note the following:

- The batches of niraparib 100mg film-coated tablets listed below have been repacked to ensure they contain the most up to date PIL.
- The specific batches have been repacked to include an updated PIL added into a clear sealable bag with a patient letter, and a copy of this Direct Healthcare Professional Communication letter.
- Discard the PIL contained within the original niraparib 100mg film-coated tablets carton.
- Refer to and provide the updated PIL which is supplied in the clear sealable bag.
- For additional copies of the Great Britain (GB) PIL, or to access the Summary of Product Characteristics (SmPC), please refer to Zejula 100mg Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) or contact the GSK Medical Information Department at ukmedinfo@gsk.com.
- The MHRA has approved this repack under a batch specific variation to the GB marketing authorisation.

Please refer to the GB ZEJULA (niraparib) 100mg film-coated tablets SmPC before prescribing.

The batch numbers/ size and expiry dates of the repacked batches are as follows:

Material Description	Batch	SLED/BBD
ZEJULA TABLET 100MG 8X7_XU	C23257	31/03/2026
ZEJULA TABLET 100MG 8X7_XU	C24008	30/06/2026
ZEJULA TABLET 100MG 12X7_XU	C23080	30/04/2025
ZEJULA TABLET 100MG 12X7_XU	C23176	31/01/2026

Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼
- 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

You can report via:

- the Yellow Card Website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 or UKSafety@gsk.com.

Company contact point
Should you have any questions or require additional information, please contact the GSK Medical Information Department on 0800 221 441, 8:30am to 5:00pm GMT, Monday – Friday, or email ukmedinfo@gsk.com.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

Dr Mark Toms MBChB FFPM
Country Medical Director, GSK UK