Pfizer Limited
Walton Oaks, Dorking Road,
Tadworth, Surrey,
KT20 7NS, UK
Telephone: +44 (0) 1304 616161

Date: 05-Jul-2024

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**Talzenna 0.25 mg capsules, hard (talazoparib):**
**Interim Supply of Northern Ireland and Ireland Stock to Mitigate Supply Disruption**

Dear Healthcare Professional,

## Summary: Pfizer Limited is currently experiencing supply disruption with Talzenna 0.25 mg capsules, hard (talazoparib) in the UK (Great Britain).

To ensure continuity in supply, Pfizer Limited has obtained approval from the MHRA to supply product from Northern Ireland (batch number 2405381; batch size 24) and Ireland (batch number 2314888; batch size 30) which is expected to be on the UK (Great Britain) market from 08-Jul-2024 to 19-Jul-2024.

Please note the following:

- This product is considered licensed in the UK (Great Britain).
- The product from Northern Ireland and Ireland has the same formulation as the UK (Great Britain) product
- The product from Northern Ireland and Ireland is manufactured according to the same manufacturing process and quality controls as the UK (Great Britain) product.
- There are differences between the Northern Ireland and Ireland product information and the UK (Great Britain) product information. Key differences are the license numbers and that packs from Northern Ireland and Ireland are shared with Germany and therefore all information is also presented in English and German. Please ensure the UK (Great Britain) Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- For additional copies of the leaflet, please refer to pil.10734.pdf (medicines.org.uk) or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Talzenna 0.25 mg hard capsules and that the information must be given in English.

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

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Below are images of the labels from the Northern Ireland and Ireland packs:



**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 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 ▼

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.

- Talzenna 0.25 mg hard capsules▼ is subject to additional monitoring. This will allow quick identification of new safety information
- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

**Company contact point**
If you have any questions about this letter or require more information about Talzenna 0.25 mg hard capsules, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616161.

Yours faithfully,

Ruhe Chowdhury Mahfuja Hussain Ruhe Chowdhury
08 Jul 2024 04:29:000-0400
REASON: I approve this document.

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Dr Ruhe Chowdhury
Oncology Medical Director UK
Pfizer Limited