

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 <u>pil.10734.pdf (medicines.org.uk)</u> 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.

Below are images of the labels from the Northern Ireland and Ireland packs: dine qozeleT\dine qozelet hard capsules/Hartkapsein 9.25 mg/0,25 mg Y Talzenna IRELAND/MALTA/UNITED KINGDOM (NORTHERN IRELAND) EN Each capsule contains talazoparib tosylate equivalent to 0.25 mg talazoparib. Read the package leaflet before Talzenna use.
Swallow whole. Do not open, crush or chew the capsules.
Keep out of the sight and reach of children. 0.25 mg/ 0,25 mg Talzenna[®] hard capsules 0:25 mg/ DE Jede Hartkapsel enthält Talazoparibtosilat, entsprechend 0,25 mg Talazoparib. Hartkapseln Deutschland talazoparib/ Talazoparib 0,25 mg rschreibungspflichtig hard capsules/Hartkapseln Packungsbeilage beachten. Im Ganzen schlucken. Die Kapseln nicht öffnen, zerdrücken oder kauen. Orai use/Zum Einnehmen 30 capsules/Kapseln talazoparib/ Talazoparib Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles/Brüssel Belgium/Belgien EU/1/19/1377/001 Arzneimittel für Kinder unzugänglich aufbewahren Zum Einnehmen 30 capsules/Kapseln PC 05415062348840 NN 15426265 Lot/Ch.-B. / EXP/Verwendbar bis / SN 7001046-1003 51 x 48 x 78 *Location of USL Security sticker when applicable sticker to be centered





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

OB Jul 2024 04:29:000-0400

REASON: I approve this document.

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Dr Ruhe Chowdhury Oncology Medical Director UK Pfizer Limited