



For the attention of Regional Procurement  
Specialists and Chief Pharmacists

12 November 2020

Dear Sir or Madam

### To Whom It May Concern

Rozlytrek ▼ (entrectinib) 100 mg and 200 mg Capsules - Missing side effect in EU Patient Information Leaflet

On 27-Aug-2020, Roche detected that for Rozlytrek, the side effect: "Increased sensitivity of the skin to sunlight" is missing in the current Patient Information Leaflet (PIL), while it is listed in the Summary of Product Characteristics (SmPC) of the product.

The following batches distributed in the UK are impacted:

Product Description	Batch Number	Expiry Date	Marketing Authorisation Number
Rozlytrek 100mg Capsules	N0013B06	Oct 2021	EU/1/20/1460/001
Rozlytrek 200mg Capsules	N1001B05	Feb 2022	EU/1/20/1460/002
Rozlytrek 200mg Capsules	N1001B19	Feb 2022	EU/1/20/1460/002

The safety assessment concluded that the missing information on photosensitivity as an adverse drug reaction in the PIL has minimal impact on the overall benefit-risk profile of Rozlytrek. Based on this assessment, Roche has decided to continue release and distribution of the impacted batches in order to ensure supply to patients, to avoid treatment interruptions, with the current PIL.



The production of re-supply with a new, corrected version of the PILs is pursued with high priority and accelerated timelines.

#### Call for reporting

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing [welwyn.uk\\_dsc@roche.com](mailto:welwyn.uk_dsc@roche.com) or calling +44 (0)1707 367554.

#### Company contact point

Tel: +44 (0)800 328 1629  
e-mail: [medinfo.uk@roche.com](mailto:medinfo.uk@roche.com)

Suspected adverse reactions:

Tel: +44 (0)1707 367554  
e-mail: [welwyn.uk\\_dsc@roche.com](mailto:welwyn.uk_dsc@roche.com)

We would be grateful if you could cascade this information within your organisation as appropriate.

Yours faithfully

Roche Products Limited