Seagen
UNITED KINGDOM

11 April 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

TUKYSA ▼ (tucatinib) 50 mg and 150 mg film-coated tablets:
Interim Supply of French or German/Austrian Stock

Dear Healthcare Professional,

Summary: Seagen is currently experiencing supply disruption with TUKYSA ▼ (tucatinib) 50 mg and 150 mg film-coated tablets in Northern Ireland.

To ensure continuity of supply, Seagen has obtained approval from the MHRA, to supply in Northern Ireland, packs from France and Germany/Austria of TUKYSA, which are expected to be on the market from April 2022 to Dec 2022.

Please note the following:

- This product is considered licensed in the Northern Ireland.
- The product from France and Germany/Austria has the same formulation as the Northern Ireland product.
- The product from France and Germany/Austria is manufactured according to the same manufacturing process and quality controls as the Northern Ireland product.
- Please ensure the Northern Ireland Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the Northern Ireland Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) supplied with this letter.
- Please discard the German or French language PIL in the pack and provide the English PIL to the patients being dispensed the product.
- For additional copies of the leaflet please refer to https://www.emcmedicines.com/en-gb/northernireland/medicines?search=tuk or contact the company at medinfoEU@seagen.com
- The combined product information for TUKYSA (including the SmPC and PIL) in English is also available from the EMA website https://www.ema.europa.eu/en/documents/product-information/tukysa-epar-product-information_en.pdf
- The expiry date and batch number are expressed on the carton and blister after “EXP” and “Lot” on French cartons and blisters, and “verwendbar bis” and “Ch.B” on German/Austrian packs, respectively.
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Tukysa 50mg and 150mg 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.

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 to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

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

Company contact point

If you have any questions about this letter, please contact Seagen at: medinfoEU@seagen.com.

Many thanks for your attention to this matter.

Yours faithfully,

Mr. Peter Martin,

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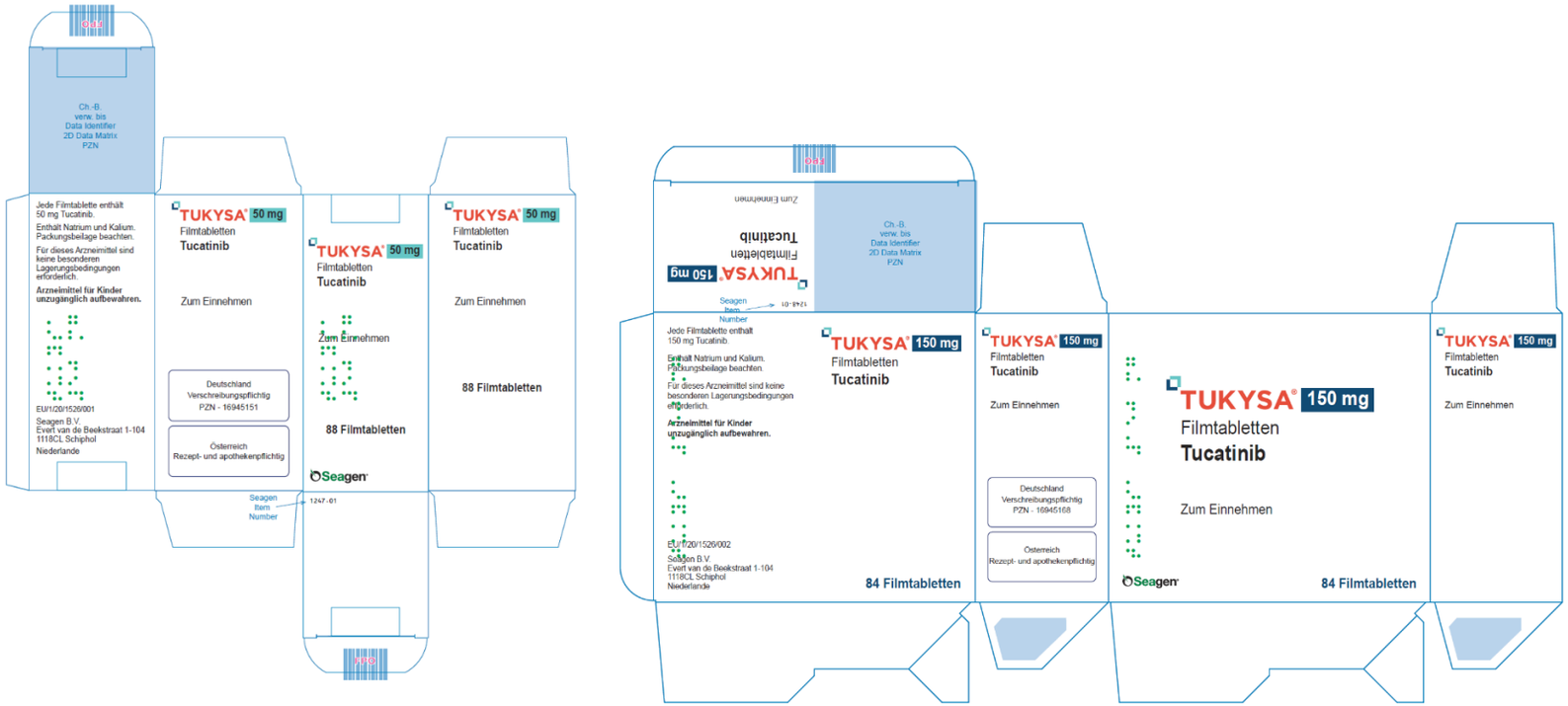
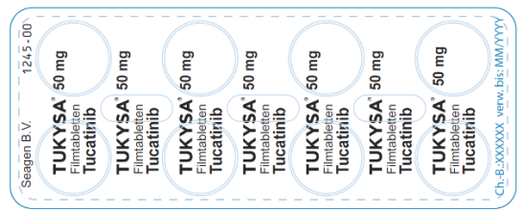
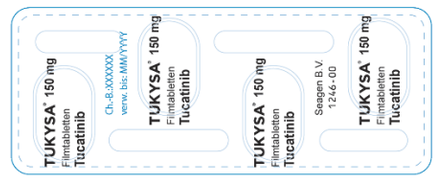
Appendix 1: German pack







Appendix 1: French pack