Direct Healthcare Professional Communication

May 2025

Dear Healthcare professional,

Zentiva Bosutinib 100mg film coated tablets PL 17780/1298

To ensure continuity of supply, Zentiva Pharma UK Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply the following batches of Zentiva **Bosutinib 100mg film coated tablets** (pack size 28 film coated tablets) with Spanish details printed on the foils.

Batch number	Expiry date
194852	12/2026
194855	12/2026

Summary

- To avoid stock shortages, Zentiva has released stock of Bosutinib 100mg tablets (pack size 28) into the market containing blisters with Spanish foils.
- The product in the Spanish blister has the same formulation as the UK product.
- The product in the Spanish blister is manufactured according to the same manufacturing process and quality controls as the UK product.
- Spanish blisters have therefore been packed into our current approved UK cartons alongside our current approved UK Patient leaflet.
- If dispensing this product, please inform the patient of this inconsistency in packaging.
- Provide reassurance to patients that there are no safety, quality or efficacy issues with these batches of Bosutinib 100mg tablets.

Details of the issue

In order to alleviate a possible stock shortage due to sourcing issues of the API and considering the products critical role in the treatment of Chronic Myeloid Leukaemia (CML), permission has been granted to use some Spanish packed stock for the UK market. This is considered to be of low risk to patients.

The two batches of product have been manufactured in line with the registered UK dossier and have passed finished product specification testing. There are no safety, quality or efficacy issues with these batches of Bosutinib 100mg tablets.

Call for reporting

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

ZENTIVA PHARMA UK LTD
Registered Address:- 12 New Fetter Lane, LONDON, EC4A 1JP
Correspondence Address:- Zentiva Pharma UK Limited, First Floor, Andrews House, College Road, Guildford, GU1 4QB UK
VAT NUMBER GB297859518

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.

Adverse events should also be reported to Zentiva Pharma UK Ltd via our online form (https://www.zentiva.co.uk/contact/mi-form), by email (UKMedInfo@zentiva.com) or by telephone (0800 090 2408).

Company contact point:
In case of any further questions please contact: Zentiva Pharma UK Ltd via our online form (https://www.zentiva.co.uk/contact/mi-form), by email (UKMedInfo@zentiva.com) or by telephone (0800 090 2408).

Yours faithfully

Janet Lewis
Head of Scientific Affairs
Zentiva Pharma UK Limited