Direct Healthcare Professional Communication

11 June 2025

Dear Healthcare Professional,

Zentiva Bosutinib 500 mg film coated tablets PL 17780/1300 – interim supply of Spanish stock to mitigate supply disruption

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 batch of Zentiva **Bosutinib 500 mg film coated tablets** (pack size 28 film coated tablets) with Spanish details printed on the foils:

500 mg film coated tablets

Batch number	Expiry date
194863	12/2026

Summary

- To avoid stock shortages, Zentiva has released stock of Bosutinib 500mg 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 the current approved UK cartons alongside the current approved UK Patient leaflet.
- If dispensing this product, please inform the patient of this inconsistency in packaging.
- Please provide reassurance to patients that there are no safety, quality or efficacy issues with the batch of Bosutinib 500mg tablets.
- Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

Details of the issue

In order to alleviate a possible stock shortage due to sourcing issues of the active substance and considering the product's critical role in the treatment of Chronic Myeloid Leukaemia (CML), permission has been granted to use some Spanish packed stock for the UK market.

The single batch of product has been manufactured in line with the registered UK dossier and has passed finished product specification testing. There are no safety, quality or efficacy issues with this batch of Bosutinib 500 mg tablets.

Background

Bosutinib is indicated for the treatment of adult patients with:

- newly diagnosed chronic phase (CP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML).
- CP, accelerated phase (AP), and blast phase (BP) Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) [TKI(s)] and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

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.

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

Signed by:
Janet Lewis
Signer Name: Janet Lewis
Signing Reason: I approve this document
Signing Time: 12-Jun-2025 | 10:50 CEST
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