Direct Healthcare Professional Communication

31-Mar-2026

Imatinib Accord 100mg and 400 mg film coated tablets (imatinib) - Missing safety information in the Patient Information Leaflet (PIL)

Dear Healthcare Professional,

Accord Healthcare Limited, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **Due to an issue with updating the Patient Information Leaflet (PIL) for Imatinib Accord 100 mg and 400 mg film-coated tablets, a safety update was missed to be included in the PIL for six batches.**
- **The rare side effect "An episode of spasm(s) and reduced consciousness (convulsions)" was erroneously omitted from Section 2 of the PIL.**
- **The quality of the tablets is not impacted as result of this issue, therefore affected batches are not being recalled.**
- **This information remains correctly included in the current SmPC section 4.8.**

Background on the safety concern

Imatinib Accord is indicated for the treatment of:

- Adult and paediatric patients with newly diagnosed Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) for whom bone marrow transplantation is not considered as the first line of treatment.
- Adult and paediatric patients with Ph+ CML in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis.
- Adult and paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.
- Adult patients with relapsed or refractory Ph+ ALL as monotherapy.
- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements.
- Adult patients with advanced hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement

Accord Healthcare Ltd has identified an error in the patient information leaflet (PIL) that has been packed in 06 batches (i.e., P2403853, P2403856, P2403859, P2403862, P2403865 and P2403868) of the product **Imatinib Accord 100 mg and 400 mg film coated tablets** due to a text consolidation error.

Consequently, the rare side effect "convulsions" was missed from the PILs of these batches. The Quality of the tablets is not impacted as result of this issue, therefore affected batches are not being recalled.

Patients rely on the PIL for the updated safety information. If this potential adverse event is missed in the PIL, the patients and caregivers may fail to recognize it as an adverse effect of imatinib leading to delayed intervention and potential injury from seizures.

However, since Imatinib is a Prescription only Medicine (POM), prescribing physicians are expected to guide and inform the patients regarding this rare but severe adverse drug reaction and for continuous monitoring of symptoms of convulsions at home.

Actions Required by Healthcare Professionals

Healthcare professionals should:

- Continue using Imatinib Accord as authorised.
- **Inform patients** about the rare possibility of seizures/spasms associated with imatinib.
- Advise patients/caregivers to seek urgent medical advice if symptoms such as:
    - sudden spasm(s),
    - reduced consciousness, or
    - convulsive episodes occur.

Please refer the corrected PIL available at: https://www.accord-healthcare-products.co.uk/document/pil-imatinib-accord-100mg-400mg-film-coated-tablets

Call for reporting

Please continue to report all suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website (www.mhra.gov.uk/yellowcard)
- the free Yellow Card app available from the Apple App Store or Google Play Store

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.

Any suspected adverse events should be reported to Accord via email to medinfo@accord-healthcare.com or by telephoning Accord Medical Information team on 01271 385257.

Company contact point

If you have any questions or for medical information enquiries, please contact Accord Medical Information Department on 01271 385257, email- medinfo@accord-healthcare.com.

Yours sincerely,

For, Accord Healthcare Limited

Paulina Rzewuska

Signed by Paulina Rzewuska, Email: paulinarzewuska@lambda-cro.com, Date: 31-Mar-2026 07:14 PM +05:30, Reason: I am the signer of this document.

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