Direct Healthcare Professional Communication

October 29, 2025

Lenalidomide Mylan (lenalidomide): potential for damaged capsules and precautionary handling measures

Dear Healthcare professional,

Mylan in agreement with the European Medicines Agency (EMA) and the <National Competent Authority > would like to inform you of the following:

Summary

- **Damaged capsules with the powder visible in the blister pocket have been identified in batches of Lenalidomide Mylan. This defect could potentially occur in all strengths and pack sizes.**
- **Visually inspect all Lenalidomide Mylan blisters upon receipt of this letter, paying special attention to the potential for damaged capsules.**
- **If a capsule is damaged, do not dispense the pack to patients and return it to the wholesaler and/or Viatris for a replacement.**
- **If the capsules are not damaged, dispense the pack to patients and ensure that the handling precautions below (see also the product information) are followed.**
- **Please ensure patients and caregivers are advised on the handling precautions and are requested to return any units they observe the subject defect in.**

Handling precautions

- **If you are pregnant or can become pregnant, do not handle lenalidomide tablets or capsules.**
- **If a capsule is damaged and you see powder in a blister pocket, do not open it. Return the blister card and box, with any remaining capsules, for replacement.**
- **Always wear disposable gloves when handling lenalidomide tablets or capsules. Then remove the gloves carefully to prevent skin exposure, place them in a sealable plastic polyethylene bag and discard them immediately. Finally, wash your hands thoroughly with soap and water.**
- **If powder from a broken lenalidomide capsule makes contact with your skin, wash the skin immediately and thoroughly with soap and water.**

- **Follow the instructions and precautions for use in the product information.**

Background information

Lenalidomide is indicated for the treatment of multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma.

Mylan received reports of damaged capsules of Lenalidomide Mylan with the powder visible in the blister pocket. An investigation was initiated, which included a review of the manufacturing process and a visual inspection of batches potentially affected. The root cause for the damage to the capsules was identified as the stationary-type channel currently in use on the blister packaging machine; this will be replaced with a different shuttle-type.

As part of the investigation, retention samples from a total of 385 batches of Lenalidomide Capsules (2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 25 mg) were inspected. The observed defect rate in the retention samples was calculated to be 0.069%.

Viatris has requested the recall of all batches where the defect was detected in the retention samples as a precautionary measure, as long as there are no drug shortage caused in the Member State involved. In Member States where the recall could not be implemented as it could result in potential shortage issues, this letter is being disseminated to inform healthcare professionals about the defect and to provide them with guidance to mitigate the potential risks associated with the defect.

This defect could potentially occur in all strengths and pack sizes which is visible as per below examples in Figure 1-2. Defect Examples:

Figure 1-2: Defect Examples

Given the teratogenic risk of the product, we ask healthcare professionals to comply with the handling precautions and instructions above.

To date, it is not known if Viatris has received any reports of adverse events related to damaged capsules.

Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system and include batch/Lot number if available. < include the details (e.g. name, postal address, phone number, website address) on how to access the national spontaneous reporting system>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Annexes

Detailed information on this medicine is available on the European Medicines Agency web site:

https://www.ema.europa.eu/en/medicines/human/EPAR/lenalidomide-mylan

Yours sincerely,

<Name> <Title>