

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Glenmark Pharmaceuticals Inc., USA is initiating a market withdrawal to the **retail level** of the below identified product batches of EZETIMIBE AND SIMVASTATIN TABLETS 10mg/10mg has been initiated by Glenmark out of an abundance of precaution because an Out of Specification result reported for test of Assay (Simvastatin Content) batch# 17221486 and 17221520 at 24 Months (Stability time point after Expiry) during long-term (25°C/60% RH) stability study. The aforementioned batches complied with the specification for all test parameters, including the assay test for both Simvastatin and Ezetimibe content till the shelf life when tested at the shelf life time point (July 2024). Hence, the batches # 17221486 and #17221520 did not warrant any market action. These batches expired in July 2024. The assay trend for Simvastatin content was observed in decreasing order towards the end of shelf life. However, no such decreasing assay trend observed for Ezetimibe content as well as impurity test results.

Further, the assay results of Simvastatin content for Annual long term stability batches were reviewed and the results were found to be within the specification limit till the shelf life time point. However, assay trend for Simvastatin content is observed in decreasing order towards the end of shelf life.

Glenmark filed CBE#-30 supplement for reduction of shelf life of the product Ezetimibe and Simvastatin tablets 10 mg/10 from 24M to 18M and the same was approved by the agency on December 9, 2024.

Since the overall trend of Simvastatin assay content of stability batches (Ezetimibe and simvastatin tablets 10/10 mg) is found to be shifting towards the lower specification side, as an abundance of caution, Glenmark is proposing the market withdrawal of all batches within shelf life, labelled with 24 months shelf life at retail level.

Please see details of product batches listed in above table and refer enclosed product labels for ease in identifying the product.

Please examine your inventory and if you have any inventory available for the batches specified in the below table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA initiated shipment of this product on May 24, 2023.

**EZETIMIBE AND SIMVASTATIN TABLETS 10 mg/10 mg (30's Pack Container)**

<b>S.No.</b>	<b>NDC</b>	<b>Batch#</b>	<b>Pack Size</b>	<b>Expiry</b>
1.	68462-321-30	17230311	30's Container	Jan-25
2.	68462-321-30	17230966	30's Container	Apr-25
3.	68462-321-30	17231197	30's Container	May-25
4.	68462-321-30	17232269	30's Container	Oct-25
5.	68462-321-30	17240158	30's Container	Dec-25
6.	68462-321-J0	17241131	30's Container	Jun-26

**EZETIMIBE AND SIMVASTATIN TABLETS 10 mg/10 mg (90's Pack Container)**

<b>S. No.</b>	<b>NDC</b>	<b>Batch#</b>	<b>Pack Size</b>	<b>Expiry</b>
1.	68462-321-90	17230311	90's Container	Jan-25
2.	68462-321-90	17230966	90's Container	Apr-25
3.	68462-321-90	17231616	90's Container	Jun-25
4.	68462-321-90	17232255	90's Container	Oct-25
5.	68462-321-90	17240158	90's Container	Dec-25
6.	68462-321-90	17241130	90's Container	Jun-26