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Batch Recall
Osteomel Once Weekly 70 mg tablets, PA 126/148/002

Lot	Expiry date
11AEYE	03/2024
11VARD	01/2025
128SHH	07/2025
12EKGC	09/2025
12LPHD	12/2025
12UEVR	03/2026
133WFA	06/2026
13EM1C	11/2026
13KRCD	12/2026
13S89A	03/2027

29th February 2024

Dear Pharmacist,

We wish to advise you that the above-listed batches of Osteomel Once Weekly 70 mg tablets are being recalled with immediate effect.

This recall is going to **pharmacy level**. This action has been agreed with the Health Products Regulatory Authority (HPRA). As this is a pharmacy level recall, you are not required to contact patients to whom the above-listed batches have been dispensed.

The reason for the recall is due to out of specification results for the parameter disintegration identified in a number of batches.

We request that you please perform the following actions:

- Immediately quarantine any units of the above-listed batches which you have in your possession. For hospital pharmacists, this includes all stock at ward or clinic level. Please make relevant staff at your facility aware of the contents of this recall notification.
- Complete the customer return form overleaf indicating the quantity of each batch in your possession and whether you would prefer replacement or credit. Please email the completed form to recall@clonmel-health.ie to arrange pick-up and credit or replacement stock. Please include a copy of the customer return form with the returned units.

- All recalled stock must be returned to Clonmel Healthcare Ltd by **Friday 16th March 2024** in order to receive credit or replacement stock.
- If you have supplied any other pharmacy, clinic, or healthcare facility with units from the above-listed batches, immediately forward a copy of this recall letter to them, requesting that they quarantine and return any units of the impacted batches to you.

Un-affected stock is available to order at this time.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Medical Information at telephone number 052 6177777. If you wish to report an Adverse Drug Event for this product, please email medicalinformation@clonmel-health.ie.

Yours sincerely,


Julia Ryan, Quality Manager

Customer Return Form

Pharmacy name: _____

Pharmacy address: _____

Pharmacy telephone number: _____

Customer Account Number: _____

Lot number	Quantity to be returned	Tick as appropriate:	
		Credit	Replacement
11AEYE			
11VARD			
128SHH			
12EKGC			
12LPHD			
12UEVR			
133WFA			
13EM1C			
13KRCD			
13S89A			

Email completed form to: recall@clonmel-health.ie