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Batch Recall

Product Name	MA No.	Batch No.	Expiry Date
Valtan 40 mg film-coated tablets	PA0126/211/001	11DHUD	04/2025
Valtan 80 mg film-coated tablets	PA0126/211/002	11EGVD	05/2025
Valtan 160 mg film-coated tablets	PA0126/211/003	11FL1A	05/2024
Amlopidine/Valsartan Clonmel 5 mg/80 mg film-coated tablets	PA0126/274/001	11FG7D	05/2023

August 5th 2021

Dear Wholesaler,

We wish to advise you that the batches of valsartan-containing film-coated tablet products listed above 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).

The recall is as a precautionary measure, due to the presence of an azide impurity above the acceptable regulatory limit.

A recall communication has also been sent to pharmacists who have been instructed to return packs to their wholesaler by August 20th 2021 to be eligible for credit.

We kindly request that you perform the following actions:

1. Immediately identify and quarantine any units of the above batches, which you have in your possession or are returned to you.
2. Identify whether you have supplied units from these batches to any other wholesaler. If you have done so, please forward a copy of this recall letter to those wholesalers, requesting that they immediately quarantine and return any unsold quantities of these batches to you.
3. Please complete the enclosed form indicating the quantity of each batch in your possession.
Please include the form with the recalled product and inform Clonmel Healthcare Ltd. who will

arrange collection. In order to receive credit please inform Clonmel Healthcare Ltd. by 03rd September 2021 if you have recalled stock to be collected.

Replacement Valtan 40 mg film-coated tablet stock is currently unavailable. Unaffected replacement stock of the other three products is available to order.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Medical Information at telephone number 052 6177777.

Yours sincerely,



Martin E Gallagher M.M.I.I.
Director of Marketing & Business Development