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### Batch Recall

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

August 5<sup>th</sup> 2021

Dear Pharmacist,

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**. Please note there is **no** requirement to contact patients, as this is a pharmacy level recall only.

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. The impurity has been recently confirmed as mutagenic. A mutagenic impurity may have the potential to be carcinogenic; however, no link has been established at present, and there is no evidence that this impurity has caused any harm to patients. This recall is being undertaken as a **precautionary measure** to prevent any further exposure to the impurity, above regulatory acceptable levels, whilst the investigation is ongoing.

#### **We kindly request that the following actions are carried out:**

1. Immediately identify and quarantine any units from the above-listed batches within your pharmacy. For hospital pharmacies, this includes units at wards, clinics and any other relevant locations within the hospital.
2. If you have supplied packs from these batches to any other pharmacy, clinic or other such establishment, please forward a copy of this recall letter to them, and request they quarantine and return any unused units to you.
3. Complete the enclosed batch recall form

4. Return the quarantined and returned units with the form to your wholesaler. Credit will be issued for packs returned by August 20<sup>th</sup> 2021.

Similar recalls are happening across Europe at this time, and patients may contact you with questions about the issue. Patients can be advised that this is a precautionary recall and that there is no immediate risk presented by the impurity. **Patients should be advised that they should not abruptly stop taking their medicine.**

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

Suspected adverse reactions should be reported to Clonmel Healthcare Ltd. by email ([medicalinformation@clonmel-health.ie](mailto:medicalinformation@clonmel-health.ie)) or to the HPRA using the [online reporting system](#).

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