Precautionary recall of blood pressure medication after packaging error

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The MHRA has advised pharmacy and healthcare professionals to return all remaining stock to their suppliers

Crescent Pharma Limited is recalling one batch of Ramipril 5 mg Capsules as a precautionary measure because a potential manufacturing error may have led to two blood pressure medicines being packaged incorrectly.

This follows a complaint from a pharmacy after a patient reported that a pack labelled Ramipril 5 mg Capsules (Batch Number GR164099) contained blister strips of Amlodipine 5 mg Tablets inside the sealed carton.

Both blood pressure medications are produced by the same manufacturer, at the same site, and the error appears to have occurred during secondary packaging of the blister strips into the cartons.

Patients who take Ramipril are advised to check the packaging of their medicine for batch number GR164099 and return any containing blister strips labelled “Amlodipine” to their pharmacist.

The risk to patients of the accidental substitution of one widely used blood pressure medication for another is low. The most likely side effect would be dizziness related to low blood pressure.

Shareen Doak, Deputy Director, Benefit-Risk Evaluation, at the Medicines and Healthcare products Regulatory Agency (MHRA) said:

> If you take Ramipril, check the packaging for batch number GR164099. The batch number and expiry date information can be found on the outer carton. If you have received this batch, check that the medication name on the carton matches the blister strips inside.
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> If the carton contains blister strips that are labelled as Amlodipine 5 mg tablets, contact your dispensing pharmacy. If the carton contains blister strips that are correctly labelled as Ramipril 5 mg Capsules, you do not need to take further action.
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> If you have an affected pack and think you may have taken the Amlodipine 5 mg Tablets that were supplied in error, and you are currently experiencing any side effects, then please seek immediate medical advice. Please take the leaflet that came with your medicine and any remaining tablets with you to your pharmacy or GP practice.
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> If you’ve already taken Amlodipine, please be reassured that there is a very low risk to your health. Both medications are used to treat high blood pressure, however because your body may not be used to a different type of medicine, your blood pressure may become lower than normal, and you may experience dizziness because of taking amlodipine. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

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Notes to editors

- Please see MHRA's Class 2 recall for further information
- The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- The MHRA is an executive agency of the Department of Health and Social Care.
- For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

https://www.gov.uk/government/news/precautionary-recall-of-blood-pressure-medication-after-packaging-error