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22nd July 2024

Subject: Recall Notification of Flolan 1.5 mg in the UK Market

Product: Flolan 1.5 mg powder and solvent for solution for infusion
Product Licence Number: PL 10949/0312

Dear Healthcare Professional,

Please find below a class 2 patient level recall notification, issued by MHRA on the 22nd of July 2024 for Flolan 1.5 mg for your attention.

Link to the MHRA recall notification : Class 2 Medicines Recall: Glaxo Wellcome UK Limited (trading as GlaxoSmithKline UK), Flolan 1.5 mg Powder and Solvent for Solution for Infusion, EL(24)A/30 - GOV.UK (www.gov.uk)

Yours sincerely,

Dr Andrea Lever

Interim Country Medical Director, UK

Medicines & Healthcare products Regulatory Agency

M E D I C I N E S R E C A L L

CLASS 2 MEDICINES RECALL

Action within 48 hours
Patient/Pharmacy/Wholesaler Level

Date: 22 July 2024 EL (24)A/30 DMRC Ref: 31259778

Dear Healthcare Professional,

Glaxo Wellcome UK Limited (trading as GlaxoSmithKline UK)

Flolan 1.5 mg Powder and Solvent for Solution for Infusion **PL 10949/0312**

SNOMED Code: 33592511000001102

Batch Number	Expiry Date	Pack Size	First Distributed
AB8M	03/2026	1	21 June 2024

Active Pharmaceutical Ingredient: epoprostenol sodium

Brief description of the problem
Glaxo Wellcome UK Ltd (GSK) has informed the MHRA that vials of Flolan 1.5 mg Powder and Solvent for Solution for Infusion, batch number AB8M may have been damaged during the packaging process. The potential damage to the vials might not be visible to the naked eye and this could compromise the integrity of the vial and quality of the medicine. As a precautionary measure GSK are recalling this batch. GSK have confirmed that no other batches are impacted, and the other batches remain available to provide immediate re-supply to patients. An investigation is underway to identify the root cause of the problem.

The MHRA and GSK have not been made aware of any adverse events related to this batch and the batch is being recalled as a precautionary measure to mitigate the risks. The information in this recall reinforces action already being undertaken by GSK and ensures that healthcare professionals in NHS Trusts and other care settings take appropriate action to recall the impacted batch from patients as soon as possible.

Advice for healthcare professionals
Stop supplying the impacted batch immediately. Quarantine all remaining stock and return it to your supplier/MAH using your supplier's approved process.

Patients and carers should be advised not to stop their medication as abrupt withdrawal can cause worsening of the condition being treated and the associated symptoms.

Majority of vials from the impacted batch have been provided to two homecare providers, who are already aware of the issue and taking appropriate actions. For other care settings including NHS trusts, GSK will ensure direct contact with the customers and initiate recall action. Steps to be taken are as below:

1. Homecare providers and Pharmacy Teams involved in dispensing this product, should identify and immediately contact all patients who have been dispensed the impacted batch to arrange recall and replacement. For non-homecare patients where batch traceability information is not available, all patients dispensed this product from 21 June 2024 should be contacted. The MHRA is aware that homecare providers will have batch traceability in place. Patients and carers should be reminded that stopping their medication abruptly can cause worsening of the condition being treated and the associated symptoms. GSK have confirmed that other batches remain available and in stock for immediate ordering.

2. Due to the considerations for re-supply related to procuring other batches, the current GSK and MHRA risk assessments consider that the benefit of continuing to use a potentially impacted vial outweighs the risks of abruptly stopping medication while waiting for an unaffected batch. In all cases, the patient's healthcare professionals should make clinical decisions based on their clinical assessment of the individual patient's needs.

3. Healthcare professionals are reminded of the recommendation for monitoring for signs and symptoms of infection, particularly where a patient has been known to have used vials from the impacted batch. An increased level of vigilance should be maintained and there should be a lower threshold for patients to seek further advice from their healthcare professional as soon as possible should they have any concerns.

4. Healthcare professionals, patients and carers should continue to examine the reconstituted solution prior to administration. Its use is forbidden in the presence of discolouration or particles. See section 4.2 of Summary of Product Characteristics (SmPC) - Method of administration. '*The reconstituted solution should be examined prior to administration. Its use is forbidden in the presence of a discoloration or particles*.' Flolan 1.5 mg Powder and Solvent for Solution for Infusion (with pH 12 solvent & Vented Vial Adaptor) - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Advice for patients

This issue is about a specific batch of Flolan 1.5 mg Powder and Solvent for Solution for Infusion vials, which may have been damaged during a packaging process. It might not be possible to see the potential damage to the vials and this could compromise the integrity of the vial and quality of the medicine. This means that there is potential for an increased risk of infections.

For this reason, the vials are being recalled as a precautionary measure; there have been no known adverse events (reported side effects) related to this batch and specific issue identified.

Your healthcare professional responsible for your care and treatment will contact you to re-supply you with Flolan 1.5 mg vials from unaffected batches. Once you have a replacement, you should return the impacted batch of Flolan 1.5 mg vials as per advice from your healthcare professional. You can contact your healthcare professional directly if you are worried, but you should keep taking your medicine as advised until you receive an alternative batch.

Never stop taking medicines such as epoprostenol (Flolan) without medical advice. Patients and carers are advised not to stop their medication as sudden withdrawal can cause worsening of the condition being treated and the associated symptoms.

In the event that alternative batches are not immediately available, your healthcare professional may suggest that you continue to use the affected batches as the benefits of doing so may outweigh the risks.

Patients who experience adverse reactions, have a sudden worsening of their clinical condition, or have any questions about medication used by you or someone you care for, should seek medical attention. If you have any concerns about your health or the health of somebody else, consult with your healthcare professional. Continue to take your medicine as prescribed.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information
Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

For more information on stock and resupply queries, contact your hospital or homecare provider. In the case of NHS trusts please contact 0800 221 441.

Should you have any questions or require additional information, please contact GSK Medical Information Department at ukmedinfo@gsk.com or alternatively contact 0800 221 441.

Yours faithfully

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