

Medicines Recall Notification

This notification requires community pharmacies to stop supplying the affected products (where applicable) as a precautionary measure. It has been developed to support the implementation of recall notifications from the <u>Medicines and Healthcare Regulatory Agency (MHRA)</u> and other agencies. Class 2 medicines recalls are defined as a defect that may cause mistreatment or harm to the patient, but it is not life-threatening or serious. Please note that a National Patient Safety Alert (NatPSA) may be issued for any type of defect that presents a risk of death or disability. Please note the Food Standards Agency (FSA) issues recall notifications for supplements with defects that may cause patient harm.

List of medicines affected

Date of recall	Medicine, strength and formulation	Manufacturer	Defect identified
<u>08/01/25</u>	Aactive D3 2000iu/ml Oral drops and Oral Solution	Trion Pharma	Excess levels of vitamin D
<u>21/01/25</u>	Tesco Health Dry Cough Relief 200ml, Asda Strong Dry Tickly Cough 200ml, Almus Dry Cough Relief & Bells Dual Action Dry Cough	Bells Healthcare	Foreign material detected in some bottles
<u>30/01/25</u>	Amlodipine 2.5 mg Tablets	Bristol Laboratories	Possible microbial contamination
<u>05/02/25</u>	Nitrofurantoin 100 mg Prolonged-Release Capsules	CNX Therapeutics	Small number of packs that contain an additional yellow tablet alongside the capsule of Nitrofurantoin

Risk of harm explained

Medicine, streng	th and	Manufacturer	Risk of harm	
Aactive D3 2000iu/ml Oral drops and Oral Solution		Trion Pharma	Excessive intakes of vitamin D can cause various adverse effects because of hypercalcaemia. Symptoms and signs may include anorexia, nausea, vomiting, weakness, lethargy, constipation and non-specific aches and pains, as well as thirst, polyuria, weight loss and cardiac dysrhythmias	
Tesco Health Dry Cough Relief 200ml, Asda Strong Dry Tickly Cough 200ml, Almus Dry Cough Relief & Bells Dual Action Dry Cough		Bells Healthcare	The contamination was identified by a single customer complaint and the investigation and analysis remains ongoing. Bells Healthcare is taking precautionary action to recall the potentially impacted batches.	
Amlodipine 2.5 mg Tablets		Bristol Laboratories	There have been no reports of patients being harmed or becoming ill from taking contaminated batches of this medicine.	
Nitrofurantoin 100 mg Prolonged-Release Capsules		CNX Therapeutics	Patients that have taken the additional tablet with the capsule have ingested a higher dose of nitrofurantoin than was intended, however, the effects are understood, and this should not have caused harm.	
Title Cla	Class 2 Medicines Recall Notification			
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Actions for community pharmacy

Trion Pharma Aactive D3 2000iu/ml Oral drops and Oral Solution

- <u>Point of sale notices</u> to be displayed in retail stores that are selling these products. This includes pictures of the affected products. These notices explain to customers why the products are being recalled and what to do if they have bought the products.
- Please refer to the <u>food recall</u> issued by the Food Standards Agency (FSA) for full details about the affected batches.
- Stop supplying the affected batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Patients who have bought any of the above products are advised not to consume them. Instead, return them to the store from where they were bought for a full refund. For more information contact TriOn Pharma on 02392 255770 or info@trionpharma.co.uk

Bells Healthcare, Tesco Health Dry Cough Relief 200ml, Asda Strong Dry Tickly Cough 200ml, Almus Dry Cough Relief & Bells Dual Action Dry Cough

- Stop supplying the listed batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Please refer to the MHRA recall for full details about the affected batches <u>Class 2 Medicines</u> <u>Recall: Tesco Health Dry Cough Relief 200ml, Asda Strong Dry Tickly Cough 200ml, Almus Dry</u> <u>Cough Relief & Bells Dual Action Dry Cough, EL(25)A/03</u>
- No action is required by patients as this is a Pharmacy, Retailer and Wholesaler level recall. Patients should be vigilant for any visible contamination and contact a healthcare professional if they have any concerns related to the product.

Bristol Laboratories Amlodipine 2.5 mg Tablets

- Stop supplying the affected batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Please refer to the MHRA recall for full details about the affected batches <u>Class 2 Medicines</u> <u>Recall Bristol Laboratories Limited Amlodipine Bristol Lab 2.5 mg Tablets</u>
- Advise patients to continue taking medicines from this batch as prescribed by their healthcare professional.

CNX Therapeutics Nitrofurantoin 100 mg Prolonged-Release capsules

- Stop supplying the affected batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Please refer to the MHRA recall for full details about the affected batches <u>Class 2 Medicines</u> <u>Recall: Nitrofurantoin CNX Therapeutics 100 mg Prolonged-Release capsules, EL(25)A/05</u>
- Should a patient present a pack containing an extra tablet, the tablet may be removed and the patient assured that the capsule is safe to take stating the extra tablet did not come from the capsule.

Please continue to record suspected adverse drug reactions to the <u>Yellow Card scheme</u>. Please continue to record medicine patient safety incidents to <u>Learning From Patient Safety Events</u>