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
Pharmacy/Wholesaler Level Recall

Date: 14 March 2023 EL (23)A/09 Our Ref: MDR 008-12/22

Dear Healthcare Professional,

The Boots Company PLC

Boots Night Cough Relief Oral Solution	**PL 00014/0230**
Boots Dry Cough Syrup 6 Years+	**PL 00014/0523**
Boots Day Cold & Flu Relief Oral Solution	**PL 00014/0565**

Thornton & Ross Limited

Cofsed Linctus	**PL 00240/0097**
Care Pholcodine 5mg/5ml Oral Solution Sugar Free	**PL 00240/0101**
Galenphol Linctus	**PL 00240/0101**
Galenphol Paediatric Linctus	**PL 00240/0102**
Galenphol Strong Linctus	**PL 00240/0103**
Covonia Dry Cough Sugar Free Formula	**PL 00240/0353**

Bell Sons & Company (Druggists) Limited

Pholcodine Linctus Bells Healthcare 5mg Per 5ml Oral Solution	**PL 03105/0059**
Numark Pholcodine 5mg per 5ml Oral Solution	**PL 03105/0059**
Well Pharmaceuticals Pholcodine 5mg per 5ml Oral Solution	**PL 03105/0059**
Superdrug Pholcodine Linctus BP	**PL 03105/0059**
Strong Pholcodine Linctus BP	**PL 03105/0060**

Pinewood Laboratories Limited

Pholcodine Linctus BP	**PL 04917/0002**
Strong Pholcodine Linctus BP	**PL 04917/0005**

LCM Limited

Pholcodine Linctus	**PL 12965/0030**

Glaxosmithkline Consumer Healthcare (UK) Trading Limited

Day & Night Nurse Capsules	**PL 44673/0068**
Day Nurse Capsules	**PL 44673/0069**
Day Nurse	**PL 44673/0075**

Brief description of the problem

Following the conclusion of a review of post-marketing safety data by the MHRA, all pholcodine-containing medicines are being recalled and withdrawn from the UK as a precaution. The Commission on Human Medicines (CHM), the independent advisory body that provides expert advice on the safety, quality and efficacy of medicines, has considered the evidence of an increased risk of the very rare event of anaphylaxis when exposed to neuromuscular blocking agents (NMBA) and advised that pholcodine-containing medicines should be withdrawn.

The available data has demonstrated that pholcodine use, particularly in the 12 months before general anaesthesia with NMBAs, is a risk factor for developing an anaphylactic reaction to NMBAs. Given the advice of the CHM, and the lack of identifiable effective measures to minimise the increased risk of anaphylactic reactions to NMBAs, pholcodine-containing medicines are being withdrawn from the UK market and will therefore no longer be available in pharmacies. All pholcodine-containing medicines are Pharmacy (P) only medicines and therefore have only been sold or dispensed under the supervision of a suitably trained healthcare professional.

Please see link to Drug Safety Update (DSU) for further information: https://www.gov.uk/drug-safety-update/pholcodine-containing-cough-and-cold-medicines-withdrawal-from-uk-market-as-a-precautionary-measure

Advice for healthcare professionals

Stop supplying the above products immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process. This recall applies to all batches currently within shelf-life for the products listed.

Healthcare professionals should recommend appropriate treatment alternatives when counselling patients who may present with symptoms of cough, cold and flu.

Pharmacists should consider recommending appropriate treatment alternatives for patients who present with a new dry cough or who are currently taking pholcodine. Where appropriate, healthcare professionals should also check whether patients who are scheduled to undergo general anaesthesia with NMBAs have used pholcodine, particularly in the previous 12 months and remain vigilant for the risk of anaphylaxis in these patients. Patients should be advised to tell their anaesthetist if they think they have previously taken pholcodine.

Advice for patients

Following a scientific review by the MHRA on pholcodine-containing medicines, which are licensed to treat dry cough in adults and children over 6 years old, it has been found that there is evidence of an increased risk of the very rare event of anaphylaxis (a sudden, severe and life-threatening allergic reaction) in surgical patients who receive general anaesthesia involving neuromuscular blocking agents (NMBA). NMBAs are used to relax the muscles during general anaesthesia for some surgical procedures. Based on advice from the independent advisory body, the Commission on Human Medicines (CHM), pholcodine-containing medicines are being withdrawn from the UK market as a precaution.

If you are taking a cough medicine (including tablets and syrups), check the packaging, label or Patient Information Leaflet to see if pholcodine is a listed ingredient – if it is, and you have any questions, you can talk to your pharmacist who can suggest a different medicine suitable for you.

Tell your anaesthetist before you have surgery if you think you have taken pholcodine, particularly in the past 12 months, or think you may have taken a pholcodine-containing product. There is no increased risk of allergic reactions, including anaphylaxis, with other allergens following pholcodine use and the absolute risk in patients who have used pholcodine is very small, but patients should talk to a pharmacist, their GP or their surgical team if they have any questions. Anaesthetists routinely manage the risk of allergic reactions during surgery.

Any suspected adverse reactions should be reported via the MHRA Yellow Card scheme.

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Further Information
For more information or, medical enquiries, please contact the respective companies below:

The Boots Company PLC
Boots Customer Care telephone 0345 0708090

Thornton & Ross Limited / LCM Limited
Email: thorntonross@medinformation.co.uk / telephone: +44 (0)1484 848164

Bell Sons & Company (Druggists) Limited
Qualified Person for Pharmacovigilance (QPPV): Mr Trevor Price – telephone: 0151 422 1216 / mobile: 07739 327 095 / email:trevor.price@bells-healthcare.com

Pinewood Laboratories Limited
Drug Safety & Information department, Wockhardt UK Limited, please email: drug.safety@wockhardt.co.uk or phone number: 01978 661261

Glaxosmithkline Consumer Healthcare (UK) Trading Limited
Contact Haleon consumer services by calling 0800 783 8881 or by emailing mystory.gb@haleon.com.

Recipients of this Medicines Recall 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.

Yours faithfully

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