



Department of
Health

An Roinn Sláinte

Máinnystrie O Poustie

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For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC/47/2020

Date: 6 October 2020

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 hours

Patient, Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

The Boots Company PLC

Boots Dermacare 1% w/w Hydrocortisone Ointment (P)

PL 00014/0364

Batch Number	Expiry Date	Pack Size	First Distributed
1DD	08/2023	15g	20 Aug 2020

Active Pharmaceutical Ingredient: hydrocortisone

Brief description of the problem

The Boots Company PLC has informed us that retained samples of the affected batch showed presence of *Pseudomonas aeruginosa* and are recalling the above batch as a precautionary measure. This product is only sold or dispensed from Boots stores and Boots online pharmacy.

P. aeruginosa is a Gram-negative bacterium; infection at the site of application could exhibit worsening of initial symptoms, and could also include erythematous lesions, irritation and pus-filled pimples. Soft tissue infection may present with abscess or cellulitis. *P. aeruginosa* infection may be more serious for immunocompromised patients and patients suffering from severe burns and cystic fibrosis.

Advice for patients and consumers

- Stop using the ointment immediately and return this to Boots Stores
- If you experience any worsening of initial symptoms and other side-effects, or have any questions or concerns about your health, speak to your doctor or pharmacist.
- Report any suspected side effects via the [Yellow Card Scheme](#)

Advice for healthcare professionals

- Stop supplying the above products immediately and remove from the shelves within your store. Quarantine all remaining stock and return them to your supplier using your supplier's approved process
- Advise patients who have been supplied this product to stop using the ointment immediately and return this to Boots Stores.
- GP practices should be aware of potential medical concerns reported by patients
- Any suspected side effects should be reported via the [Yellow Card Scheme](#)

Advice for retailers and wholesalers

- Stop supplying the above products immediately. Quarantine all remaining stock and return them to your supplier using your supplier's approved process

Further Information

For stock control and medical information enquiries please contact 0115 9595165

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



Mrs Cathy Harrison
Chief Pharmaceutical Officer