



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**  
**Distribute to Pharmacy / Wholesaler Level**

Date: 10 March 2022

EL (22)A/12

Our Ref: MDR 176-02/22

Dear Healthcare Professional,

**Boots Company Plc.**

**Decongestant Tablets**

**PL 00014/0375**

Batch Number	Expiry Date	Pack Size	First Distributed
2008662A	30/09/23	12 Tablets	18/12/20
2008662C	30/09/23	12 Tablets	28/05/21
2109523A	30/09/24	12 Tablets	07/10/21
2109523B	30/09/24	12 Tablets	17/11/21
2111550A	30/11/24	12 Tablets	26/11/21

**Active Pharmaceutical Ingredient:** Pseudoephedrine hydrochloride

**Decongestant with Pain Relief Tablets**

**PL 00014/0594**

Batch Number	Expiry Date	Pack Size	First Distributed
2006973	30/06/23	12 Tablets	30/08/21
2110262	31/10/24	12 Tablets	14/12/21
2110264A	31/10/24	12 Tablets	13/12/21

**Active Pharmaceutical Ingredient:** Paracetamol, Pseudoephedrine hydrochloride

### **Brief description of the problem**

Boots have identified an error with the printed patient information leaflet provided with batches of the above-mentioned products.

Please see missing information from the PIL(s) (in bold):

#### Section 'Do not take':

- if you are pregnant **or breastfeeding**

#### Section 'Talk to your pharmacist or doctor if you experience':

- **Sudden abdominal pain or rectal bleeding may occur with this medicine, due to inflammation of the colon (ischaemic colitis). If you develop these gastro-intestinal symptoms, stop taking**



**this medicine and contact your doctor or seek medical attention immediately. See 'Possible side effects' section.**

- **Reduction of blood flow to your optic nerve may occur with pseudoephedrine. If you develop sudden loss of vision, stop taking this medicine and contact your doctor or seek medical attention immediately. See 'Possible side effects' section.**

Section 'Possible side effects':

If you get any of these serious side effects, stop taking the tablets. See a doctor at once:  
Frequency not known:

- **Inflammation of the colon due to insufficient blood supply (ischaemic colitis).**
- **Reduced blood flow to the optic nerve, loss of vision (Ischaemic optic neuropathy)**

**Advice for healthcare professionals**

Healthcare professionals should ensure that appropriate patient counselling takes place and patients are aware of the missing information.

Please provide a replacement PIL printed from eMC.com with each sale of the product. Web links provided below.

- Decongestant Tablets, PL 00014/0375
  - <https://www.medicines.org.uk/emc/product/8292/pil>
- Decongestant with Pain Relief Tablets, PL 00014/0594:
  - <https://www.medicines.org.uk/emc/product/1566/pil>

This issue only impacts Boots Stores, however other healthcare professionals should be aware of the missing information and provide patient support/advice as necessary. Boots Company Plc have confirmed that all stock currently in their warehouse has been suppressed from sale and will not be sent to store or sold onwards. All suspected side effects should also be reported via the [Yellow Card Scheme](#).

**Further Information**

For medical information and stock control queries please contact: [UKRegulatory@boots.co.uk](mailto:UKRegulatory@boots.co.uk)

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.

Yours faithfully

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