

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy Level

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 gastrointestinal 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

Recipients of this Medicines Notification 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.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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10th March 2022

Pharmaceutical website: <http://www.hscbusiness.hscni.net>