



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  
Mrs Cathy Harrison  
Castle Buildings  
Upper Newtownards Road  
Belfast BT4 3SQ

Telephone: 028 90 523219  
Facsimile: 028 90 522335

E-Mail: [cathy.harrison@health-ni.gov.uk](mailto:cathy.harrison@health-ni.gov.uk)

Our Ref: PHC/10/2020  
Date: 20 February 2020

## **DRUG ALERT**

### **CLASS 4 MEDICINES DEFECT INFORMATION**

**Caution in Use**

**Distribute to Pharmacy Level**

Dear Healthcare Professional

**Crescent Pharma Ltd**

**Ibuprofen 400mg Tablets (Almus Livery)**

**PL 20416/0089**

| <b>Batch Number</b> | <b>Expiry Date</b> | <b>Pack Size</b> | <b>First Distributed</b> |
|---------------------|--------------------|------------------|--------------------------|
| DO3210N             | 09.2022            | 84               | 11 Jun 19                |
| DO3310N             | 09.2022            | 84               | 07 Aug 19                |
| DO3410N             | 09.2022            | 84               | 11 Jun 19                |
| DO3510N             | 09.2022            | 84               | 11 Jun 19                |
| DO3610N             | 10.2022            | 84               | 18 Jul 19                |
| DO3710N             | 10.2022            | 84               | 12 Mar 19                |
| DO3811N             | 10.2022            | 84               | 12 Mar 19                |
| DO3911N             | 10.2022            | 84               | 19 Jul 19                |

**Ibuprofen 400mg Tablets (Crescent Livery)**

**PL 20416/0089**

| <b>Batch Number</b> | <b>Expiry Date</b> | <b>Pack Size</b> | <b>First Distributed</b> |
|---------------------|--------------------|------------------|--------------------------|
| 001205M             | 04.2021            | 84               | 08 Aug 19                |
| DO0101O             | 12.2022            | 84               | 10. Jan 20               |
| DO0503O             | 02.2023            | 84               | 10 Jan 20                |

**Flamingo Pharma (UK) Ltd**

**Ibuprofen 400mg Tablets (Flamingo Pharma Livery)**

**PL 43461/0005**

| <b>Batch Number</b> | <b>Expiry Date</b> | <b>Pack Size</b> | <b>First Distributed</b> |
|---------------------|--------------------|------------------|--------------------------|
| 1402177             | Aug-23             | 24               | Oct-18                   |
| 1402268             | Sep-23             | 48               | Nov-18                   |
| 1402278             | Oct-23             | 24               | Dec-18                   |
| 1402308             | Nov-23             | 84               | Dec-18                   |
| 1402309             | Nov-23             | 84               | Dec-18                   |
| 1402310             | Nov-23             | 84               | Dec-18                   |
| 1402316             | Nov-23             | 84               | Jan-19                   |
| 1402317             | Nov-23             | 84               | Jan-19                   |
| 1402318             | Dec-23             | 24               | Jan-19                   |
| 1402337             | Dec-23             | 48               | Jan-19                   |
| 1402338             | Dec-23             | 48               | Jan-19                   |
| 1402363             | Dec-23             | 48               | Mar-19                   |
| 1402353             | Dec-23             | 48               | Mar-19                   |
| 1402354             | Dec-23             | 48               | Mar-19                   |
| 1402352             | Dec-23             | 84               | Mar-19                   |
| 1402361             | Dec-23             | 84               | Mar-19                   |
| 1402362             | Dec-23             | 84               | Mar-19                   |
| 1402368             | Jan-24             | 48               | Mar-19                   |
| 1402369             | Jan-24             | 24               | Mar-19                   |
| 1402370             | Jan-24             | 24               | Mar-19                   |
| 1402424             | Mar-24             | 24               | Apr-19                   |
| 1402425             | Mar-23             | 48               | Apr-19                   |
| 1402543             | May-24             | 48               | Jul-19                   |
| 1402544             | May-24             | 48               | Jul-19                   |
| 1402554             | Jun-24             | 24               | Jul-19                   |
| 1402557             | Jun-24             | 84               | Aug-19                   |
| 1402558             | Jun-24             | 48               | Aug-19                   |
| 1402559             | Jun-24             | 48               | Aug-19                   |
| 1402622             | Jul-24             | 48               | Sep-19                   |
| 1402623             | Jul-24             | 48               | Sep-19                   |
| 1402624             | Jul-24             | 24               | Sep-19                   |
| 1402625             | Jul-24             | 24               | Sep-19                   |
| 1402628             | Jul-24             | 24               | Sep-19                   |
| 1402670             | Aug-24             | 24               | Nov-19                   |
| 1402671             | Aug-24             | 24               | Nov-19                   |
| 1402672             | Aug-24             | 24               | Nov-19                   |
| 1402673             | Aug-24             | 24               | Nov-19                   |
| 1402674             | Sep-24             | 48               | Nov-19                   |
| 1402686             | Sep-24             | 48               | Nov-19                   |
| 1402687             | Sep-24             | 48               | Nov-19                   |
| 1402688             | Sep-24             | 48               | Nov-19                   |
| 1402705             | Sep-24             | 48               | Nov-19                   |
| 1402706             | Sep-24             | 84               | Nov-19                   |
| 1402707             | Oct-24             | 48               | Dec-19                   |
| 1402708             | Oct-24             | 48               | Dec-19                   |
| 1402709             | Oct-24             | 84               | Dec-19                   |
| 1402710             | Oct-24             | 84               | Dec-19                   |
| 1402711             | Nov-24             | 84               | Jan-20                   |
| 1402837             | Dec-24             | 24               | Feb-20                   |
| 1402838             | Dec-24             | 24               | Feb-20                   |
| 1402854             | Dec-24             | 48               | Feb-20                   |

|         |        |    |        |
|---------|--------|----|--------|
| 1402839 | Dec-24 | 96 | Feb-20 |
| 1402852 | Dec-24 | 96 | Feb-20 |
| 1402853 | Dec-24 | 84 | Feb-20 |

### Ibuprofen 400mg Tablets (TEVA Livery)

PL 43461/0005

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| 1402172      | Jul-23      | 84        | Sep-18            |
| 1402173      | Jul-23      | 84        | Sep-18            |
| 1402174      | Aug-23      | 84        | Oct-18            |
| 1402175      | Aug-23      | 84        | Oct-18            |
| 1402176      | Aug-23      | 84        | Oct-18            |
| 1402178      | Aug-23      | 84        | Oct-18            |
| 1402279      | Nov-23      | 84        | Dec-18            |

### Brief description of the problem

Crescent Pharma Ltd and Flamingo Pharma (UK) Ltd have informed us that the Patient Information Leaflet (PIL) within their packs for the above pharmacy (P) batches is incorrect. The PIL in the above batches includes incorrect dosing instructions in Section 3, How to take Ibuprofen. The leaflet incorrectly states that 'The maximum daily dose should not exceed 6 [six] tablets (2400 mg).' This dosing regimen should only be given to patients who are under the supervision of their GP or healthcare prescriber and have been prescribed Ibuprofen 400mg Tablets. The outer carton contains the correct P indications and posology.

### Advice for healthcare professionals

When dispensing or providing this product over the counter, please check the Marketing Authorisation Holder and the batch number; if any of the above batch numbers are being dispensed, ensure that patients are aware of the correct dosage instructions and maximum daily dose as stated on the carton labelling.

- **Correct statement: The maximum daily dose should not be more than 3 [three] tablets (1200 mg).**

Where possible, these packs should be considered to be dispensed against a prescription rather than sold over the counter to safeguard patients from taking a prescription only dose.

### Further Information

#### Crescent Pharma Ltd.

- For updated PIL information, please click the link below: <https://www.crescentpharma.com/wp-content/uploads/2020/02/m132-leaflet-pl-20416-0089-Crescent-MHRA-accepted-06.02.2018.pdf>
- For more information or medical information queries, please contact: Crescent Pharma Ltd. Medical Information Department on +00351 214643225, via email on [tiago.barca@pharsolution.com](mailto:tiago.barca@pharsolution.com) or +44 (0) 1256 772740.

#### Flamingo Pharma (UK) Ltd.

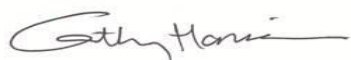
- For more information or medical information queries, please contact: Flamingo Pharma (UK) Ltd on +44 (0) 7733 522465

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

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

A handwritten signature in black ink, appearing to read 'Cathy Harrison', written in a cursive style.

Mrs Cathy Harrison  
Chief Pharmaceutical Officer