

## DRUG ALERT

### CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy Level

Dear Healthcare Professional

Crescent Pharma Ltd

PL 20416/0089

Ibuprofen 400mg Tablets (Almus Livery)

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| DO4212N      | Nov-22      | 84        | 19/07/2019        |
| DO3911N      | Oct-22      | 84        | 19/07/2010        |
| DO3811N      | Oct-22      | 84        | 12/03/2019        |
| DO3710N      | Oct-22      | 84        | 12/03/2019        |
| DO3610N      | Oct-22      | 84        | 18/07/2019        |
| DO3510N      | Sep-22      | 84        | 11/06/2019        |
| DO3410N      | Sep-22      | 84        | 11/06/2019        |
| DO3310N      | Sep-22      | 84        | 07/08/2019        |
| DO3210N      | Sep-22      | 84        | 11/06/2019        |
| DO3110N      | Sep-22      | 84        | 16/04/2019        |
| DO1303N      | Feb-22      | 84        | 08/10/2018        |
| DO1003N      | Feb-22      | 84        | 12/07/2018        |
| DO0902N      | Feb-22      | 84        | 12/07/2018        |

PL 20416/0089

Ibuprofen 400mg Tablets (Crescent Livery)

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| DO4312N      | Dec-22      | 84        | 25/11/2019        |
| DO3010N      | Sep-22      | 84        | 11/12/2019        |
| DO1705O      | Apr-23      | 84        | 07/10/2019        |
| DO1605O      | Apr-23      | 84        | 18/10/2019        |
| DO1505O      | Apr-23      | 84        | 01/10/2019        |
| DO1405O      | Apr-23      | 84        | 01/10/2019        |
| DO1305O      | Apr-23      | 84        | 27/12/2019        |
| DO1205O      | Apr-23      | 84        | 09/09/2019        |
| DO1104O      | Apr-23      | 84        | 27/12/2019        |

|         |        |    |            |
|---------|--------|----|------------|
| DO1004O | Mar-23 | 84 | 09/09/2019 |
| DO0904O | Mar-23 | 84 | 21/11/2019 |
| DO0804O | Mar-23 | 84 | 21/11/2019 |
| DO0703O | Mar-23 | 84 | 15/11/2019 |

|         |        |    |            |
|---------|--------|----|------------|
| DO0603O | Feb-23 | 84 | 15/11/2019 |
| DO0503O | Feb-23 | 84 | 20/01/2020 |
| DO0403O | Feb-23 | 84 | 15/11/2019 |
| DO0101O | Dec-22 | 84 | 25/11/2019 |
| 001205M | Apr-21 | 84 | 08/08/2019 |

**Flamingo Pharma (UK) Ltd**

**PL 43461/0005**

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

| <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 |

PL 43461/0005

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

| 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.

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

**TO ALL CHEMISTS, DOCTORS ON THE LISTS**

Pharmaceutical Services  
2 Franklin Street  
BELFAST  
BT2 8DQ

Telephone No. 028 9536 0333

**26<sup>th</sup> February 2020**

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