



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 20 February 2020

EL (20)A/10

Our Ref: MDR 051-09/19

Dear Healthcare Professional,

Crescent Pharma Ltd

Ibuprofen 400mg Tablets (Almus Livery)

PL 20416/0089

Batch Number	Expiry Date	Pack Size	First Distributed
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

Batch Number	Expiry Date	Pack Size	First Distributed
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

Batch Number	Expiry Date	Pack Size	First Distributed
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 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.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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