Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy, Retail and Wholesaler Level

Date: 20 July 2020 EL (20)A/030 Our Ref: MDR 054-07/20

Dear Healthcare Professional,

Aspar Pharmaceuticals Limited

Product	Pack Size(s)	PL number
Aspar Ibuprofen 200mg Caplets **(GSL)**	16	PL 08977/0015

Product	Pack Size(s)	PL number
Nisa Ibuprofen Tablets BP 200mg **(GSL)**	16	PL 08977/0016
Lloyds Pharmacy Ibuprofen 200mg Tablets **(GSL)**	16	
Lloyds Pharmacy Ibuprofen200mg Tablets **(P)**	24, 48, 96	
Lifestyle Ibuprofen Tablets BP 200mg **(GSL)**	16	
Ibucalm 200mg Tablets **(GSL)**	16	
Ibucalm 200mg Tablets **(P)**	24, 48, 96	
Careway Ibuprofen 200mg Tablets **(GSL)**	16	
Careway Ibuprofen 200mg Tablets **(P)**	24, 48	
Asda Ibuprofen 200mg Tablets **(P)**	48	

Product	Pack Size(s)	PL number
Ibucalm 400mg Tablets **(P)**	24, 48, 96	PL 08977/0017
Asda Ibuprofen 400mg Tablets **(P)**	48, 96	
Careway Ibuprofen 400mg Tablets **(P)**	24, 48	
Lloyds Pharmacy Ibuprofen 400mg Tablets **(P)**	12, 24, 48, 96	

Active pharmaceutical ingredient: ibuprofen

Brief description of the problem
Aspar Pharmaceuticals Limited has informed us that the Patient Information Leaflets (PILs) within the ibuprofen packs above are missing some information identified from post-marketing experience that should be documented in Section 3 (How To Take The Tablets) and Section 4 (Possible Side Effects) of the PIL.

Section 3 (How To Take The Tablets)

Current information in the PIL	Correct information that should be included in the PIL
Seek medical attention IMMEDIATELY if you accidentally take too many tablets.	Seek medical attention IMMEDIATELY if you accidentally take too many tablets. *If you have taken more than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.* *The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.*

Section 4 (Possible Side Effects)

Current information in the PIL	Correct information that should be included in the PIL
(No appropriate wording related to DRESS syndrome)	*A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).*

Aspar Pharmaceuticals Limited has taken corrective steps to update the PIL going forward.

Advice for healthcare professionals
If any of the above products are supplied and/or dispensed, please ensure that patients are aware of the missing information as highlighted above. It is important that any patients who notice the above symptoms should seek immediate medical advice.

As a general reminder, patients who experience side effects from taking any medicines should be encouraged to report a suspected problem or incident via the Yellow Card scheme (www.mhra.gov.uk/yellowcard) and seek medical advice accordingly.

Further Information
For more information or medical information queries, please contact:
Aspar Pharmaceuticals
Acrewood Way, Hatfield Road, St Albans, AL4 0JY, Hertfordshire
Tel: 020 8205 9846

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

NHS England and NHS Improvement Regional Offices are asked to forward this alert to community pharmacy contractors.

Yours faithfully

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