



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 03 February 2022

EL (22)A/05

Our Ref: MDR 005-01/22

Dear Healthcare Professional,

Atnahs Pharma UK Limited

Naprosyn 250mg Tablets

Naprosyn 500mg Tablets

Naprosyn EC 250mg Gastro-Resistant Tablets

PL 43252/0004

PL 43252/0005

PL 43252/0006

Product Name	Batch No	Expiry Date	Pack Size	First Distributed
Naprosyn EC 250mg Tablets	E0174E1	Feb-22	56	Jun-19
Naprosyn 250mg Tablets	E0098E1	Feb-24	56	Jun-19
Naprosyn 250mg Tablets	E0097E1	Jun-23	56	May-19
Naprosyn 500mg Tablets	E0961E1	Feb-24	56	Sep-20
Naprosyn 500mg Tablets	E0960E1	Feb-24	56	Apr-20
Naprosyn 500mg Tablets	E0959E1	Feb-24	56	Nov-19
Naprosyn 500mg Tablets	E0958E1	Feb-24	56	Oct-19
Naprosyn 500mg Tablets	E0946E2	Sep-23	56	May-19
Naprosyn 500mg Tablets	E0965E1	Apr-23	56	Jun-19

Active Pharmaceutical Ingredient: naproxen

Brief description of the problem

Atnahs Pharma UK Limited have informed us that the Patient Information Leaflets (PILs) that have been provided with the above batches are missing the following information (in **bold**):

Section 2: Other medicines and Naprosyn Tablets

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. In particular tell you doctor or pharmacist if you are taking:

Medicine to stop your blood clotting, like **aspirin/acetylsalicylic acid**, warfarin, heparin or clopidogrel



Advice for healthcare professionals

There is no risk to the product quality as a result of this issue, therefore the affected batches are not being recalled.

Healthcare professionals are advised to exercise caution when dispensing this product. Please check the Marketing Authorisation Holder and the batch number; if any of the above batch numbers are being dispensed, please provide an updated PIL. The updated PILs are available via the electronic Medicines Compendium website:

[Naprosyn 250mg Tablets PIL](#)

[Naprosyn 500mg Tablets PIL](#)

[Naprosyn EC 250mg Gastro-Resistant Tablets PIL](#)

Healthcare professionals should also remind patients to seek medical advice if taking aspirin/acetylsalicylic acid with Naprosyn Tablets or Naprosyn EC Gastro-Resistant Tablets, due to the increased risk of bleeding when these medicines are taken concurrently. Patients who experience adverse reactions should seek immediate medical attention. Any suspected adverse reactions should be reported via the [MHRA Yellow Card scheme](#)

Atnahs Pharma UK Limited have confirmed that all other batches of Naprosyn Tablets and Naprosyn EC Gastro-Resistant Tablets contain the correct PILs.

Further Information

For more information, medical information queries or stock control queries, please contact:

info@pharmanovia.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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