

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy Level

Dear Healthcare Professional

Atnahs Pharma UK Limited

Naprosyn 250mg Tablets

Naprosyn 500mg Tablets

Naprosyn EC 250mg Gastro-Resistant Tablets

Naprosyn EC 500mg Gastro-Resistant Tablets

PL 43252/0004

PL 43252/0005

PL 43252/0006

PL 43252/0008

Product Name	Batch Number	Pack Size	Expiry Date	First Distributed
Naprosyn 250mg Tablets	E0098E5	56 tablets	Feb-24	Jul-19
Naprosyn 250mg Tablets	E0098E6	56 tablets	Feb-24	Oct-19
Naprosyn 250mg Tablets	E0102E1	56 tablets	Jul-24	Nov-19
Naprosyn 250mg Tablets	E0102E2	56 tablets	Jul-24	Feb-20
Naprosyn 250mg Tablets	E0103E1	56 tablets	Sep-24	Feb-20
Naprosyn EC 250mg Gastro-Resistant Tablets	E0174E2	56 tablets	Feb-22	Dec-19
Naprosyn EC 250mg Gastro-Resistant Tablets	E0183E1	56 tablets	Apr-22	Apr-20
Naprosyn EC 250mg Gastro-Resistant Tablets	E0186E2	56 tablets	Mar-22	Aug-20
Naprosyn EC 250mg Gastro-Resistant Tablets	E0187E1	56 tablets	Mar-22	Oct-20
Naprosyn EC 250mg Gastro-Resistant Tablets	E0188E1	56 tablets	Mar-22	Jul-21
Naprosyn EC 250mg Gastro-Resistant Tablets	E0188E4	56 tablets	Mar-22	Aug-21
Naprosyn EC 250mg Gastro-Resistant Tablets	E0189E2	56 tablets	Mar-22	Nov-20
Naprosyn EC 250mg Gastro-Resistant Tablets	E0190E1	56 tablets	Mar-22	Nov-19
Naprosyn EC 250mg Gastro-Resistant Tablets	E0191E1	56 tablets	Mar-22	Aug-20
Naprosyn 500mg Tablets	E0962E1	56 tablets	Apr-24	Aug-20
Naprosyn 500mg Tablets	E0963E1	56 tablets	Apr-24	Sep-20
Naprosyn 500mg Tablets	E0964E1	56 tablets	Apr-23	Apr-19
Naprosyn 500mg Tablets	E0965E2	56 tablets	Apr-23	Jul-19
Naprosyn 500mg Tablets	E0972E1	56 tablets	Apr-24	Aug-20
Naprosyn 500mg Tablets	E0973E1	56 tablets	Apr-24	Sep-20
Naprosyn 500mg Tablets	E0974E1	56 tablets	Apr-24	Oct-19
Naprosyn 500mg Tablets	E0975E1	56 tablets	Apr-24	Nov-21

Naprosyn EC 500mg Gastro-Resistant Tablets	E0596E1	56 tablets	Mar-22	Nov-19
Naprosyn EC 500mg Gastro-Resistant Tablets	E0601E1	56 tablets	Apr-22	May-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0601E4	56 tablets	Apr-22	Aug-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0615E1	56 tablets	Apr-22	Aug-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0622E1	56 tablets	Jun-22	Feb-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0623E1	56 tablets	Jun-22	Feb-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0626E1	56 tablets	Jun-22	Jul-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0627E1	56 tablets	Jun-22	Nov-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0628E1	56 tablets	Jun-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0628E2	56 tablets	Jun-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0632E3	56 tablets	Jul-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0633E2	56 tablets	Jul-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0634E3	56 tablets	Jul-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0635E2	56 tablets	Jul-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0636E1	56 tablets	Jul-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0637E1	56 tablets	Jul-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0640E2	56 tablets	Jul-22	Mar-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0656E1	56 tablets	Aug-22	Nov-20
Naprosyn EC 500mg Gastro-Resistant Tablets	E0657E1	56 tablets	Aug-22	Feb-22
Naprosyn EC 500mg Gastro-Resistant Tablets	E0658E1	56 tablets	Sep-22	Jan-22
Naprosyn EC 500mg Gastro-Resistant Tablets	E0665E1	56 tablets	Sep-22	Oct-21
Naprosyn EC 500mg Gastro-Resistant Tablets	E0666E1	56 tablets	Sep-22	Oct-21

Active Pharmaceutical Ingredient: naproxen

Brief description of the problem

Additional to the batches included in the previous Class 4 Medicines Notification (reference [PHC-5-2022](#)), Atnahs Pharma UK Limited have informed us that the Patient Information Leaflets (PILs) in 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 these 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](#)
[Naprosyn EC 500mg 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. Hard copies of the updated PIL could be provided by the MAH upon request, so that any affected batch remaining in the dispensary can be supplemented with the updated PIL.

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

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

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28th February 2022

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