



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 28 February 2022

EL (22)A/09

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
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 |



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|--|---------|------------|--------|--------|
| 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 [EL\(22\)A/05](#)), 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. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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