MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(26)A/21

Action within 5 days

Issued 23 April 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Omega Pharma Ltd

MEDICINE DETAILS

Napralief 250mg Gastro-Resistant Tablets

PL: **02855/0340**

Active Ingredient: **naproxen**

SNOMED code: N/A

GTIN: **05012616268236**

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
B51496	31/10/2028	9 Tablets	31/12/2025
B51497	31/10/2028	9 Tablets	03/02/2026
B51102	31/10/2028	9 Tablets	23/12/2025

Background

Omega Pharma Ltd is recalling specific batches of Napralief 250mg Gastro-Resistant Tablets due to missing text in Section 2 and Section 3 of the Patient Information Leaflet (PIL) and on the Carton in packs of Napralief 250mg Gastro-resistant tablets.

The Carton is missing the following wording:

- Adults (18-50 years): On the first day take two tablets, followed by one tablet 6-8 hours later, if needed. If required on the second and third day, take one tablet every 6-8 hours.
- **Do not take more than three tablets a day.**

The PIL (Patient Information Leaflet) is missing the following wording highlighted in bold:

Section 2. What you need to know before you take Napralief Tablets. Warnings and precautions Talk to your doctor or pharmacist before taking Napralief® Tablets:	1. If you have **or have had** heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have or **have had high** blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist. **2. A mixed connective tissue disease** or an autoimmune condition, such as 'systemic lupus erythematosus' (SLE), which causes joint pain, skin rashes and fever. **3.** Skin reactions. Serious skin reactions **including severe rashes with blistering, peeling of the skin (exfoliative dermatitis)** Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Naproxen Tablets. **These reactions are most likely to occur in the first weeks of treatment.** **4. If you develop visual disturbances while taking Napralief® you should have an eye examination.** **5. Serious allergic reactions can occur with Napralief®, even if you have never had an allergy to painkillers before. See section 4.** **6. If you need any blood or urine tests tell your doctor you are taking Napralief® Tablets. The tablets may need to be stopped 48 hours before a test, as they may interfere with the results.**
3. How to take Napralief Tablets	Adults (18-50 years) **First day of treatment** Initially take two tablets (500 mg) then if needed, one tablet (250 mg) after 6-8 hours. **Second and third day of treatment** **If needed, take one tablet (250 mg) every 6-8 hours.** **Do not take more than the maximum dose of three tablets a day**.

Advice for Healthcare Professionals:

Stop supplying the above batches immediately. Quarantine all stock and return it to your supplier using your supplier's approved process.

Advice for Healthcare Professionals to Provide to Patients:

Do not take more than three tablets per day.

Patients should be aware that the Patient Information Leaflet (PIL) and Carton in certain batches of Napralief 250mg Gastro-resistant tablets do not contain the most up to date safety information and should refer to the correct information listed above.

No further action is required by patients. This recall is being undertaken as a precautionary measure and applies at Pharmacy and Wholesaler level.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For all medical information enquiries, stock control queries and information on this product, please email UKLOcustomerservice@perrigo.com or call +44 0203 598 9603.

Recipients of this Medicines Recall 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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