Precautionary recall of medication used for pain and inflammation due to incomplete patient information

23.4.2026 - | Her Majesty's Revenue and Customs

Specific batches of Napralief 250mg Gastro-Resistant Tablets are being recalled because important safety and dosage information is missing from both the patient information leaflet and the outer carton.

Omega Pharma Limited is recalling specific batches of Napralief 250mg Gastro-Resistant Tablets as a precautionary measure due to important safety and dosage information being missing from the patient information leaflet (PIL) and outer carton.

Napralief 250mg contains the active ingredient naproxen and is a non-steroidal anti-inflammatory drug (NSAID) used to treat muscle or joint pain, such as sprains and strains, inflammation caused by sporting injuries, lower back pain, neck pain or pain in the wrists or feet. It is also used to treat period pain.

Three batches are affected by this recall. These can be identified by checking the packaging for batch numbers B51496, B51497, and B51102.

The affected cartons do not include the instruction that patients must not take more than three tablets a day, which is a key dosage safety message intended to prevent overuse.

In addition, the PIL is missing dosage instructions which state that on the first day patients should take two tablets, followed by one tablet 6-8 hours later. For the second and third day of treatment, if needed, one tablet (250mg) should be taken every 6–8 hours.

The PIL is also missing advice that patients should have an eye examination if they develop visual disturbances, warnings that serious allergic reactions can occur even in people with no previous allergy to painkillers, and guidance to inform a doctor if blood or urine tests are needed, as treatment may need to be stopped 48 hours before testing.

In addition, some information relating to heart problems and associated risk factors, certain autoimmune or mixed connective tissue diseases, and potential serious skin reactions is also missing. As a result of these omissions, patients may not receive the full information required to use the medicine safely.

Dr Alison Cave, MHRA Chief Safety Officer, said:

“Napralief 250mg is considered safe when used in line with the correct dosage instructions. Although small unintentional dosing mistakes are usually not harmful, complete and accurate safety information is essential to help ensure patients use their medicine correctly.

“Patients can continue to use the medicine safely in line with the correct safety and dosage instructions. Patients should take two tablets on the first day, followed by one tablet 6-8 hours later. For the second and third day of treatment, if needed, one tablet should be taken every 6–8 hours. Napralief should not be taken for more than three days.”

Patients experiencing any adverse effects or with questions about their medication should seek medical advice. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

The MHRA has advised healthcare professionals to stop supplying the affected batches and return all remaining stock to their suppliers.

Notes to editors

- Please see MHRA's Class 3 recall for further information.
- The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- The MHRA is an executive agency of the Department of Health and Social Care.
- For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

https://www.gov.uk/government/news/precautionary-recall-of-medication-used-for-pain-and-inflammationdue-to-incomplete-patient-information