

Caution In Use Notification

Controlled Drug

Oxycontin 20 mg Tablets (56 pack)

PA number: PA1688/005/003

Batch Number 255243, Expiry Date 04/2025

30/03/2023

Dear Pharmacist,

Following discussions with the HPRA we wish to alert you of the following:

A number of packs of the above batch of product have been identified which are missing blister strips.

As the product is in short supply, this batch is not currently being recalled.

However, the pharmacist at your premises is kindly requested to perform the following actions:

1. Identify any unopened packs of the above batch in your possession.
2. Open the packs and check the number of blister strips contained within the pack.
3. If less than 4 blister strips are present, you may wish to return the pack to your wholesaler for replacement. These packs should be clearly marked as being defective.
4. With regard to the required FMD Safety Feature checks for these packs:
 - a. Before the packs are opened, please perform a verification scan of the 2D barcodes to verify that the packs are authentic.
 - b. Before the packs are opened, please check the integrity of the Anti-tamper Device on the packs to verify that the packs are integral.
 - c. The decommissioning scan can be performed at the time the packs are being dispensed or returned.

With regard to packs of this batch that your pharmacy may receive going forward, please note the following:

- Packs from this affected batch will continue to be supplied until the batch is exhausted from wholesalers. This may take several weeks.
- These packs should be checked by the pharmacist, either upon receipt or before dispensing, to check that they contain 4 blister strips. Please carry out steps 2 – 4 above.

Please ensure that your Controlled Drugs Register is updated to reflect any returns or partially filled packs.



The Pharmaceutical Society of Ireland (PSI) has been informed of the issue.

An investigation is currently ongoing by the manufacturer as to the cause of the quality defect. Packs from this batch are currently being checked at wholesale level.

New batches that do not have the quality defect will be available from May 2023

We apologise for any inconvenience this issue may cause. Should you have any queries please contact:

Bernard Lawlor

Responsible Person Quality

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087 9789667

Graham Hodge

National Business Manager

graham.hodge@mundipharma.ie

086 3875991

Yours sincerely

A handwritten signature in blue ink, appearing to read "Graham Hodge". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Graham Hodge

National Business Manager

Mundipharma Pharmaceuticals