



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Retail Stores / Pharmacy / Wholesaler Level

Date: 20 July 2022

EL (22)A/32

Our Ref: MDR 041-07/22

Dear Healthcare Professional,

Omega Pharma Limited

Niquitin 14mg Clear Patch

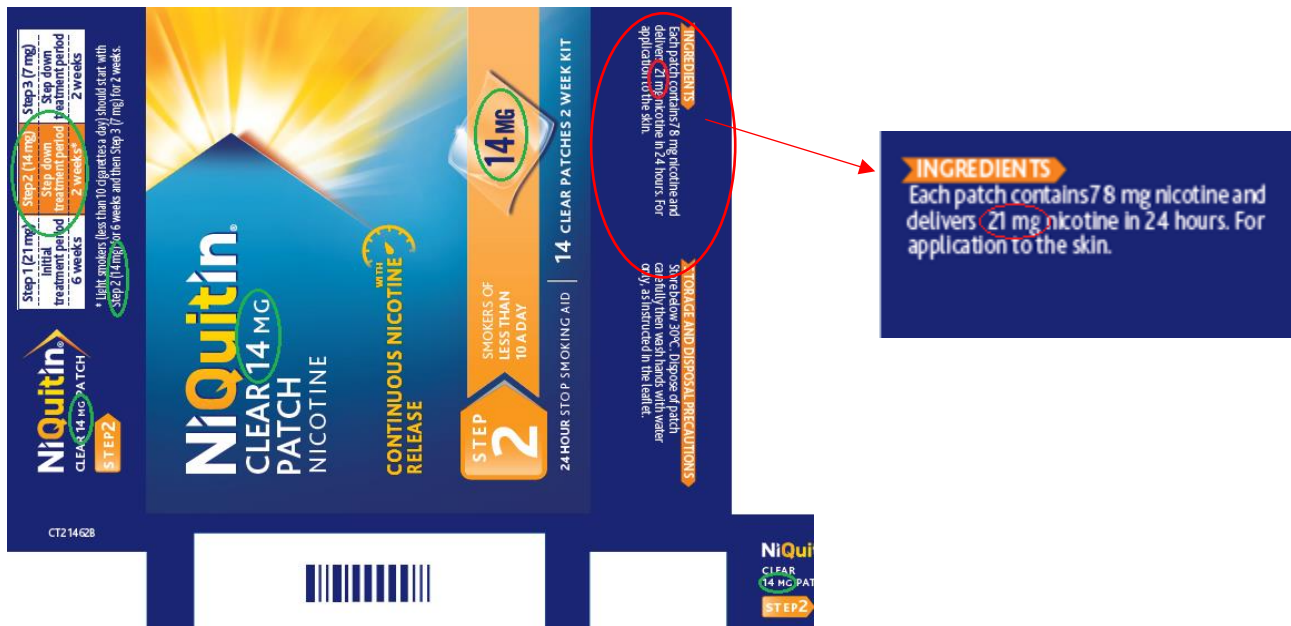
PL 02855/0251

| Batch No | Expiry Date | Pack Size | First Distributed |
|----------|-------------|------------|---------------------|
| 0370102 | Aug-2024 | 14 patches | 08-Jun-2022 |
| 1110101 | Mar-2025 | 14 patches | Not Distributed Yet |

Active Pharmaceutical Ingredient: Nicotine

Brief description of the problem

Omega Pharma Limited have identified an error relating to the product packaging. In the 'Ingredients' section on the base of the carton, the patch dosage is stated as providing 21mg of nicotine per day. The correct dosage is 14mg per day. The other dosage indications on the carton, the sachets, PIL and SmPC are correct. There is no issue with the product quality and the batch is not being recalled.





Medicines & Healthcare products
Regulatory Agency

Advice for healthcare professionals and retailers

Healthcare professionals and other retailers are advised to note the error relating to the product packaging and where possible should refer to the dose on the other areas of the carton or sachet which remains correct. As stated above, each patch provides 14mg of nicotine per day and this information should be used when using this product.

Since all batches are within specification and there are no quality issues with the product, the batches on hold awaiting distribution will be sold and have been included in this notification for information. Omega Pharma Limited have confirmed that only these two batches are impacted and all future batches will be packaged with the correct carton.

Advice for patients

Patients are advised to note the error relating to the product packaging and are not required to take any further action at this time. The medicine itself is not affected and each patch provides 14mg of nicotine per day. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Further Information

For medical information and stock control queries please contact: uklocustomerservice@perrigo.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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk