



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 31 May 2022

EL (22)A/26

Our Ref: MDR 024-04/22

Dear Healthcare Professional,

DEMO SA PHARMACEUTICAL INDUSTRY

Esomeprazole 40mg Powder for Solution for Injection/Infusion PL 55035/0001

Batch No	Expiry Date	Pack Size	First Distributed
2200855	12/2023	1 vial per box	01/03/2022

Active Pharmaceutical Ingredient: esomeprazole

Brief description of the issue

DEMO SA PHARMACEUTICAL INDUSTRY has informed us that the Product Code/GTIN (PC) number found on the above batch is incorrect. The GTIN number that should have been allocated for this batch is 5200040321010, however, 05026468771424 was applied in error which scans the batch as Acetylcysteine 200mg/ml injection (2g/10ml ampoules).

The product packed, patient information leaflet (PIL), and other primary data on the outer carton were confirmed as correct for Esomeprazole 40 mg powder for solution for injection and infusion, therefore this is batch is not subject to a recall.

There may be residual risk in cases where wholesalers and pharmacies use automated inventory system to dispense the affected batch within the pharmacy or wholesale facility.

Advice for healthcare professional

- The GTIN barcode should not be used for any dispensing activities for the affected batch listed above. Please bring this notice to the attention of all relevant staff within your facility.
- If you have supplied units from this batch to any other pharmacy or clinic, please forward a copy of this Alert to them.

Advice for wholesalers

- The GTIN barcode should not be used for any dispensing activities for the affected batch listed above. Please bring this notice to the attention of all relevant staff within your facility.
- If you have supplied units from this batch to any other pharmacy or clinic, please forward a copy of this Alert to them.

Advice for patients

There is a barcode error on the outer packaging of the product. The medicine itself is not affected and patients do not need to take any action.

Further Information

For medical information or stock control queries please contact Pantelis Krithimos at pkrithimos@demo.gr



Medicines & Healthcare products
Regulatory Agency



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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