Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 07 August 2024 EL (24)A/34 DMRC Ref: 31246876

Dear Healthcare Professional,

Sandoz Limited

Omeprazole 10mg gastro-resistant capsules PL 04416/0651

SNOMED Code: 3753411000001102

Batch Number	Expiry Date	Pack Size	First Distributed
NR7436	31/08/2025	28	24/06/2024
NP0188	31/08/2025	28	23/04/2024

Omeprazole 20mg gastro-resistant capsules PL 04416/0652

SNOMED Code: 3753611000001104

Batch Number	Expiry Date	Pack Size	First Distributed
NK2790	31/05/2025	100	24/04/2024
NP6341	31/10/2025	28	11/07/2024
NP0340	30/09/2025	28	30/06/2024
NP0338	30/09/2025	28	26/06/2024
NP0196	31/08/2025	28	30/05/2024
NP6261	30/09/2025	28	03/07/2024
NP6340	30/09/2025	28	05/07/2024
NP0192	31/08/2025	28	29/04/2024
NN5783	31/08/2025	28	28/03/2024
NN7643	30/09/2025	28	13/06/2024
NM4605	31/08/2025	28	18/03/2024
NM1246	31/07/2025	28	17/03/2024
NK4294	31/07/2025	28	24/02/2024
NK2489	31/07/2025	28	12/03/2024
NM1246	31/07/2025	28	17/03/2024
NK2486	31/07/2025	28	20/02/2024
NK2484	30/06/2025	28	19/01/2024
NJ0183	31/07/2025	28	01/02/2024
NJ0182	31/07/2025	28	22/01/2024
NJ6114	31/07/2025	28	16/02/2024
NJ5014	31/07/2025	28	28/02/2024

NJ6113	31/07/2025	28	14/02/2024
NJ0179	30/06/2025	28	18/01/2024
NJ0180	30/06/2025	28	19/01/2024
NJ0181	30/06/2025	28	29/01/2024
NH7770	31/07/2025	28	22/01/2024
NH7771	30/06/2025	28	17/01/2024
NH2809	30/06/2025	28	11/01/2024
NG8624	31/05/2025	28	08/01/2024
NG8998	31/05/2025	28	01/12/2023
NG8621	31/05/2025	28	01/12/2023
NG4125	31/05/2025	28	12/12/2023
NG4126	31/05/2025	28	21/12/2023
NG2539	31/05/2025	28	27/11/2023
NW2409	30/11/2025	28	Not yet distributed
NP6341	31/10/2025	28	Not yet distributed
NP6342	31/10/2025	28	Not yet distributed
NR2911	31/10/2025	28	Not yet distributed
NT3562	31/10/2025	28	Not yet distributed
NT4728	31/10/2025	28	Not yet distributed
NT7236	30/11/2025	28	Not yet distributed

Mezzopram 10mg dispersible gastro-resistant tablets **PL 04416/1077**

SNOMED Code: 18503211000001105

Batch Number	Expiry Date	Pack Size	First Distributed
NT9384	30/06/2025	28	Not yet distributed
NS2301	30/06/2025	28	13/06/2024
NM8348	30/04/2025	28	06/03/2024
NG6059	31/12/2024	28	04/01/2024
NE9955	31/10/2024	28	04/09/2023
NX3026	31/10/2025	28	Not yet distributed

Mezzopram 20mg dispersible gastro-resistant tablets **PL 04416/1078**

SNOMED Code: 18503311000001102

Batch Number	Expiry Date	Pack Size	First Distributed
NR1768	30/04/2025	28	09/05/2024
NR1766	30/04/2025	28	05/04/2024
NH0584	31/12/2024	28	11/12/2023
NH0585	31/12/2024	28	22/01/2024
NJ8635	31/12/2024	28	16/01/2024
NH0587	31/12/2024	28	29/11/2023
NH0583	31/10/2024	28	19/10/2023

Mezzopram 40mg dispersible gastro-resistant tablets PL 04416/1079

SNOMED Code: 18503411000001109

Batch Number	Expiry Date	Pack Size	First Distributed
NR1765	31/10/2025	7	28/03/2024
NC2107	31/12/2024	7	16/07/2023

Omeprazole 40mg powder for solution for infusion vials PL 04416/0701

SNOMED Code: 31685111000001103

Batch Number	Expiry Date	Pack Size	First Distributed
NH1463	31/07/2025	1	30/05/2024
NH1462	31/07/2025	1	04/06/2024
NH1464	31/07/2025	1	09/01/2024
NF5853	28/02/2025	1	26/10/2023
NA0066	28/02/2025	1	11/08/2023
NA0068	28/02/2025	1	02/11/2023
NA0074	28/02/2025	1	08/02/2024
NK2237AA	31/08/2025	1	Not yet distributed

Active Pharmaceutical Ingredient: Omeprazole

Brief description of the problem
Sandoz Ltd. has informed the MHRA that there is missing safety information in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPCs) of the specific products listed in this notification. The product information does not include a warning/precaution for severe cutaneous adverse reactions (SCAR) in section 4.4, and adverse events of drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) in section 4.8 of the SmPC.

Advice for healthcare professionals
There is no risk to product quality or safety of the medicines because of this missing information. Therefore the affected batches are not being recalled. Due to supply considerations, batches listed as not yet distributed will not be repackaged with the updated PIL prior to distribution. The specified 'Not yet distributed' batches are scheduled to be distributed in the future to avoid any supply considerations

Healthcare professionals are advised to review the information contained within this notification and take this into account when prescribing. If any of the above products are supplied and/or dispensed, please ensure that patients are aware of the missing information as highlighted above. It is important that any patients who notice relevant symptoms (see information in the 'Advice for Patients' section) should seek immediate medical advice. The following is a link to the updated SmPC:

Omeprazole 10mg gastro-resistant capsules (PL 04416/0651):
Omeprazole 10mg Capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Omeprazole 20mg gastro-resistant capsules (PL 04416/0652):
Omeprazole 20mg Capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Mezzopram 10mg dispersible gastro-resistant tablets (PL 04416/1077):
Mezzopram 10 mg Dispersible Gastro-resistant Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Mezzopram 20mg dispersible gastro-resistant tablets (PL 04416/1078):
Mezzopram 20 mg Dispersible Gastro-resistant Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Mezzopram 40mg dispersible gastro-resistant tablets (PL 04416/1079):
Mezzopram 40 mg Dispersible Gastro-resistant Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Omeprazole 40mg powder for solution for infusion vials (PL 04416/0701):
Omeprazole 40 mg Powder for Solution for Infusion - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Advice for patients
Omeprazole can very rarely cause certain conditions that result in skin reactions like widespread rashes, peeling skin, scaly skin, bumps, blisters, or redness. These conditions can also cause other symptoms like fever and swollen lymph nodes, which you can feel as lumps under the skin. These conditions are known as 'drug reaction with eosinophilia and systemic symptoms' (DRESS) and 'acute generalized exanthematous pustulosis' (AGEP), and they occur in about 1 out of every 10,000 to 1,000 patients taking omeprazole. Information about these conditions is missing from the Patient Information Leaflet that comes with your medicine. This does not change or affect the quality of the product, you can safely continue your treatment. Should you experience any skin reactions during or after treatment, or if you have any other unusual symptoms such as high temperature, lumps or feeling unwell please contact your healthcare professional as soon as possible.

If you have any concerns about the information provided with your medicine, please speak with your pharmacy team in the first instance. If you have concerns about a medicine you may be using, please contact your healthcare professional.

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.

Further Information
For more information or medical information queries, please email sandozgb@EU.propharmagroup.com, or telephone: +44 1276 698 101

For stock control queries, please email sales.sandoz-gb@sandoz.com, or telephone: +44 1276 698607

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

Medicines & Healthcare products Regulatory Agency

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