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: 26 September 2024 EL (24)A/43 DMRC Ref: 32698072

Dear Healthcare Professional,

Sandoz Limited

Risperidone 1mg Tablets PL 04416/0662

SNOMED Code: 38913811000001102

Batch Number	Expiry Date	Pack Size	First Distributed
NK4910	Jul-2026	20	12-Feb-2024

Active Pharmaceutical Ingredient: risperidone

Risperidone 1mg Tablets PL 04416/0662

SNOMED Code: 38913811000001102

Batch Number	Expiry Date	Pack Size	First Distributed
NK4909	Aug-2026	60	17-Jan-2024

Active Pharmaceutical Ingredient: risperidone

Risperidone 2mg Tablets PL 04416/0663

SNOMED Code: 20891211000001105

Batch Number	Expiry Date	Pack Size	First Distributed
NL4679	Oct-2026	60	12-Jan-2024

Active Pharmaceutical Ingredient: risperidone

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Risperidone 3mg Tablets **PL 04416/0664**

SNOMED Code: 20894411000001106

Batch Number	Expiry Date	Pack Size	First Distributed
MM5115	Jul-2025	60	03-Mar-2024
NE5508	Mar-2026	60	09-Aug-2024

Active Pharmaceutical Ingredient: risperidone

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 (SmPC) for Risperidone 1mg, 2mg and 3mg and Tablets. The PIL and SmPC does not include the Adverse event of Stevens Johnson's syndrome and toxic epidermal necrolysis in section 4.8 Adverse drug reactions for the MedDRA System Organ Class 'Skin and subcutaneous tissue disorders'.

The missing information on the Risperidone 1mg, 2mg and 3mg Tablets PIL and SmPC is as follows:

Adverse Drug Reactions (ADRs) by System Organ Class and Frequency		
MedDRA System Organ Class	Frequency	ADRs
Skin and subcutaneous tissue disorders	Common	Rash, Erythema
	Uncommon	Urticaria, Pruritus, Alopecia, Hyperkeratosis, Eczema, Dry skin, Skin discolouration, Acne, Seborrhoeic dermatitis, Skin disorder, Skin lesion,
	Rare	Drug eruption, Dandruff
	Very rare	Angioedema
	Not known	Stevens-Johnson syndrome/toxic epidermal necrolysis[c]

[c] Not observed in risperidone clinical studies but observed in post-marketing environment with risperidone.

Advice for healthcare professionals
There is no risk to product quality or impact to safety of the medicines listed in this notification because of this missing information. Healthcare professionals are advised to review the content of this notification, as it provides information that is missing from the current label and take this into account when prescribing. If the medicines listed in this notification are supplied or dispensed, ensure that patients are aware of the missing information displayed above. It is important to advise patients that if patients experience any of the above symptoms they should seek immediate medical advice.

Refer to updated SmPC as follows:

SmPC, Risperidone 1mg Tablets, PL 04416/0662
https://www.medicines.org.uk/emc/product/11871/smpc

SmPC, Risperidone 2mg Tablets, PL 04416/0663
https://www.medicines.org.uk/emc/product/11872/smpc

SmPC, Risperidone 3mg Tablets, PL 04416/0664
https://www.medicines.org.uk/emc/product/11873/smpc

Sandoz Ltd. has confirmed that all future batches will contain the correct PIL. Upon request, Sandoz Ltd. will post hard copies of the updated PIL to pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information (see contact details below).

Advice for patients
Patients do not need to take any action. The information above is missing from the Patient Information Leaflet. The missing information, summarised in this notification, does not change or affect the quality of the product. Therefore you can safely continue your treatment. However, should you experience any adverse effects/side effects with the prescribed medication 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 medical information queries, please contact: sandozgb@EU.propharmagroup.com, Telephone: +44 1276 698 101.

For stock control queries, please contact: sales.sandoz-gb@sandoz.com , 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

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