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**IMMEDIATE MESSAGE TO:**

1. Directors of Pharmacy
2. Medical Directors NHS Boards

26 September 2024

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 DRUG ALERT 43 2024 – CLASS 4 MEDICINES DEFECT  
INFORMATION – CAUTION IN USE – SANDOZ LTD – RISPERIDONE 1MG, 2MG AND  
3MG**

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

**IRENE FAZAKERLEY**  
**Medicines Policy Team**





# MEDICINES NOTIFICATION

## 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



## 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 <sup>c</sup>

<sup>c</sup> 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.



## Medicines & Healthcare products Regulatory Agency

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](mailto:sandozgb@EU.propharmagroup.com), Telephone: +44 1276 698 101.

For stock control queries, please contact: [sales.sandoz-gb@sandoz.com](mailto: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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