PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

28 February 2025

Risperidone (Risperdal®, Rispone®) 1 mg/ml Oral Solution: Risk of medication errors leading to accidental overdoses in children and adolescents

Dear Healthcare Professional,

Janssen Sciences Ireland UC and Rowex Ltd., in agreement with the Health Products Regulatory Authority, would like to inform you of the following:

Summary

- **The European Medicines Agency (EMA) has reviewed reports of medication errors and accidental overdoses involving risperidone oral solution in children and adolescents aged 3–15 years, with a mean age of 8.8 years[*].**
- **The majority (74%) of reported overdose cases were serious. The most frequent incidents were linked to decimal point errors, resulting in 10-fold overdosing.**
- **These errors were primarily attributed to small dose volumes prescribed for the paediatric population (0.25–1.5 ml) which may cause confusion when adminstered with dosing devices which can contain much larger volumes.**
- **It should be noted there is variability in dosing devices across different risperidone liquid products.**
- **Healthcare professionals are advised to provide clear guidance to caregivers and patients on the correct use of dosing devices and emphasise the importance of reading the package leaflet to ensure safe and accurate dosing.**
- **This is particularly important given the potential severity of administering an incorrect dose, particularly in the paediatric population.**

[*] Risperdal/Rispone is not licensed in children younger than 5 years.

Background on the safety concern

Risperidone is a second-generation antipsychotic drug (atypical antipsychotic). For children and adolescents, it is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.

There are other licensed indications in adults.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has completed a review of reports of medication errors and accidental overdoses involving risperidone oral solution in paediatric patients aged 3-15 (mean age of 8.8 years).

The majority (74%) of reported cases of overdose were serious with decimal point errors, leading to 10-fold overdoses, identified as the most frequent type of error.

Symptoms reported in the overdose cases were largely consistent with those listed in section 4.9 of the Risperdal®/Rispone® Summary of Product Characteristics (SmPC). These include drowsiness, sedation, tachycardia, hypotension, extrapyramidal symptoms, QT prolongation and convulsions. While no fatal cases were reported, cardiovascular and central nervous system events, particularly QT prolongation and convulsions, can be life-threatening for vulnerable patient groups.

The potential causes for medication errors identified in the PRAC review included:

- Caregiver misinterpretation of the dosing device. These errors were primarily attributed to small dose volumes prescribed for the paediatric population (0.25–1.5 ml) which may cause confusion when adminstered with dosing devices which can contain much larger volumes.
- Variability in the dosing devices provided with different risperidone liquid products.

<u>Instructions for patients and caregivers on the correct use of the dosing device delivered with risperidone oral solution</u>

Pharmacists should:

- Advise the caregiver/patient to carefully read the package leaflet.
- Provide clear guidance on how to read the dosing scale, highlighting where to take volume readings on the syringe. Particular attention should be paid to differences in scale positions, such as on the plungers versus the syringe body.
- Demonstrate how to measure small volumes.
- Advise the caregiver/patient to use only the dosing device supplied with the product.
- Emphasise the importance of rinsing the dosing device with plain water and on letting it air dry after each use.
- **Advise caregivers/patients to urgently seek medical attention in case of overdose or if overdose symptoms occur.**

Following the PRAC review, updates will be made to the instructions for patients and caregivers in the product information for risperidone-containing oral solutions including highlighting the need for vigilance when measuring small dose volumes.

Call for reporting

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77. Telephone + 353-1-6764971, website: www.hpra.ie; E-mail medsafety@hpra.ie. Reports of suspected adverse reactions can also be made to the companies, contact details below.

Please report the product name and batch details.

Company contact point

If you have any questions, or if you require any further information, please contact the medical information service of the relevant Marketing Authorisation Holder:

Marketing Authorisation Holder	**Product /name**	**Email Address**	**Phone number**
Janssen Sciences Ireland UC	Risperidone (Risperdal® 1mg/ml Oral solution®)	medinfo@its.jnj.com	1 800 709 122
Rowex Ltd.	Risperidone (Rispone® 1mg/ml oral solution)	pv@rowa-pharma.ie	027 50077

Yours faithfully,

Le Roux Zoe
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