

Ref: 02/2026/PLD  
19th May 2026

## **Risperidone 1 mg/ml Oral Solution: Risk of medication errors leading to accidental overdoses in children and adolescents**

Dear Healthcare Professional,

VJ Salomone Pharma Ltd and Mint Health Ltd, in agreement with the Malta Medicines 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 administered 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 emphasize 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.**

## ***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 disorders of children and adolescents.

There are other licensed indications for 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 Risperidone 1mg/ml Oral Solution 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 administered with dosing devices which can contain much larger volumes.
- Variability in the dosing devices provided with different risperidone liquid products.

### Instructions for patients and caregivers on the correct use of the dosing device delivered with risperidone oral solution

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***

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form available online at <http://medicinesauthority.gov.mt/adrportal> and sent to Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

Healthcare Professionals may also report any adverse events associated with the use of risperidone-containing oral solutions to the relevant Marketing Authorisation Holder contact points.

### ***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:

| <b>Marketing Authorisation Holder</b> | <b>Product /name</b>              | <b>Email Address</b>   | <b>Phone number</b> |
|---------------------------------------|-----------------------------------|--|---------------------|
| VJ Salomone Pharma Ltd                | Risperidone 1mg/ml Oral Solution  | <a href="mailto:regvjsp@vjsalomone.com">regvjsp@vjsalomone.com</a>                   | +356 21 220 174     |
| Mint Health Ltd                       | Risperidone 1 mg/ml Oral Solution | <a href="mailto:pharmacovigilancemt@mint.com.mt">pharmacovigilancemt@mint.com.mt</a> | +356 2093 9800      |

### ***Disclaimer***

*This Direct Healthcare Professional Communication has been submitted to you on behalf of Rosemont Pharmaceuticals Ltd and Mint Health Ltd*

*The MMA receives the relevant contact details from both the Medical Council and the Pharmacy Council. Should you wish to amend your details including address, you are asked to contact the Medical Council or Pharmacy Council directly, as may apply.*

*For more information related to safety please refer to the below:*

Archived Safety Circulars are available from: <https://medicinesauthority.gov.mt/safetycirculars>

Archived Direct Healthcare Professional Communications are available from: <https://medicinesauthority.gov.mt/dhpc>

Archived additional Risk Minimisation Measures are available from: <https://medicinesauthority.gov.mt/rmm>