

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

30/04/2026 | Circular Number P01/2026

Information on Risperidone 1 mg/ml Oral Solution

- 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.
- There are other licensed indications in adults

In Malta the following products are authorised through national licensing procedures

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
RISPERIDONE 1 milligram(s)/millilitre	Risperdal 1mg/ml oral solution'	ORAL SOLUTION	POM	MA018/00204	Janssen-Cilag International NV
RISPERIDONE 1 milligram(s)/millilitre	Risperidone 1mg/ml Oral Solution '	ORAL SOLUTION	POM	MA1296/00801	Syri Pharma Limited
RISPERIDONE 1 milligram(s)/millilitre	Eperon 1 mg/ml oral solution '	ORAL SOLUTION	POM	MA032/15801	Medochemie Limited
RISPERIDONE 1 milligram(s)/millilitre	Risperidone 1mg/ml Oral Solution	ORAL SOLUTION	POM	AA1173/08901UK	Mint Health Limited
RISPERIDONE 1 milligram(s)/millilitre	Risperidone 1mg/ml Oral Solution	ORAL SOLUTION	POM	AA1488/06701UK	HHP Malta (P&D Pharma) Limited
RISPERIDONE 1 milligram(s)/millilitre	Risperidone 1mg/ml Oral Solution	ORAL SOLUTION	POM	AA288/01002UK	V J Salomone Limited

Information from the EMA about 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 Summary of Product Characteristics (SmPC) of Risperidone. 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.

About the procedure

This review was carried out as part of a signal assessment procedure. For more information on signals refer to [EMA website](#)

In Malta

For Healthcare Professionals

HCPs administering risperidone oral solution should be aware of the risk of medication administration errors leading to potential accidental overdoses. Ensure a suitable dosing device capable of measuring a small dose [e.g., 0.25–1.5 ml] is used.

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.**

Advice for Patients

The solution comes with a syringe. Use only the syringe delivered with this medicine for measuring the dose prescribed by the doctor. Measure the exact dose of medicine you need. **Pay attention when measuring a small dose, for example for 0.25 mg, measure 0.25 ml (a quarter millilitre); for 0.5 mg, measure 0.5 ml (half a millilitre).**

In case of overdose the person may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats or fits. Children are more susceptible to side effects, meaning even a slight overdose of risperidone can cause serious adverse reactions. If you or your child gets any side effects, talk to your doctor.

Caregivers/patients should urgently seek medical attention in case of overdose or if overdose symptoms occur.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on **Risperidone Oral Solution**. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

**Post-Licensing Directorate
Malta Medicines Authority**

Healthcare professionals and patients are encouraged to regularly check the Malta Medicines Authority website for product safety updates as these are issued on an ongoing basis.

[Archived Safety Circulars](#)

[Archived Direct Healthcare Professional Communications](#)

[Archived Risk Minimisation Measures](#)

Feedback Form

The Malta Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Malta Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required)

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Pharmacovigilance Section

Post-Licensing Directorate

Malta Medicines Authority

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