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Risperidone-containing medicines 1 mg/mL in oral solution formulation: medication error associated with accidental overdose in children and adolescents

Dear Healthcare professional,

The Marketing Authorisation Holders of risperidone-containing medicines 1 mg/mL in oral solution formulation, in agreement with the Italian Medicines Agency (AIFA), would like to inform you of the following:

Summary

- **Cases of accidental overdose** have been reported **in paediatric patients** treated with risperidone 1 mg/mL oral solution following administration errors due to **misinterpretation of the graduated scale on the dosing device.**
- It is important to provide clear instructions on how to correctly measure small volumes of the medicinal product by ensuring that the graduated scale of the device is correctly interpreted.
- **It is important to inform parents and/or carers of patients about:**
    - Carefully read the package leaflet before use;
    - Only use the syringe or pipette provided with the medicine;
    - Wash the syringe or pipette with plain water and on letting it air dry after each use.;
    - Tell your doctor immediately in case of overdose or onset symptoms such as drowsiness, sedation, tachycardia, hypotension or convulsions.

Background

Risperidone is a second-generation atypical antipsychotic. For children aged 5 years and older and in 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.
A European signal procedure was started, following reports of accidental overdose in children and adolescents treated with risperidone 1 mg/mL oral solution. The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) found that approximately **74% of cases** were severe, and in most cases, the dose administered was **up to 10 times higher** than the prescribed dose.
The most frequently reported symptoms were consistent with those described in section 4.9 "Overdose" of the Summary of Product Characteristics (SmPC): drowsiness, sedation, tachycardia, hypotension, extrapyramidal symptoms, QT prolongation and convulsions.

The main causes of therapeutic error were identified as:

- Difficulty in reading and interpreting the device markings by caregivers, especially for small volumes (0.25–1.5 mL);
- Variability in dosing devices provided with different medicinal products containing risperidone in oral solution formulation.

After considering the available evidence, the PRAC concluded that:

- all marketing authorisation holders for medicinal products containing risperidone 1 mg/mL oral solution formulation must have dosing devices with clearly legible 0.25 mL intervals;
- package leaflets must be amended to include clear illustrations showing how to measure smaller volumes correctly.

Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with the use of risperidone-containing medicines 1 mg/mL in oral solution formulation in accordance with the national spontaneous reporting system at the following address: https://www.aifa.gov.it/en/content/segnalazionireazioni-avverse