AGENZIA ITALIANA DEL FARMACO

Signals Management Office

SAFETY COMMUNICATION OF THE ITALIAN MEDICINES AGENCY (AIFA)

Medicinal products containing RISPERIDONE, in oral solution formulation, and cases of accidental overdose following administration errors in paediatric patients and adolescents

The Italian Medicines Agency (AIFA) draws attention to the importance of administering the correct dose of medicines containing risperidone in oral solution formulation, with particular reference to the treatment of paediatric and adolescent patients.

The communication is made following reports of accidental overdose of risperidone, in the oral solution formulation, in children and adolescents aged between 1 and 17 years. In some reports, serious events were reported, which required access and observation in hospital facilities. However, all cases had a favourable outcome.

In those cases where the cause of the accidental overdose could be traced, it was linked to a misinterpretation of how to use the dosing device (dosing syringe) supplied with the oral solution formulation, with the result that some patients were given up to 10 times the prescribed dose.

Overdose can lead to serious adverse events especially affecting the CNS, cardiovascular and gastrointestinal levels, such as drowsiness, sedation, tachycardia, hypotension, extrapyramidal symptoms, vomiting, QT interval prolongation and convulsions.

To avoid further administration errors and to reduce the risk of overdose, **prescribers and pharmacists are advised to carefully instruct parents and/or carers on how to measure the exact dose to be administered and to ensure that they understand it correctly. In case of any doubts about the use of the medicine, parents and/or carers should consult their doctor or pharmacist**.

We would also like to take this opportunity to point out that medicines containing risperidone are not indicated for use in children under 5 years of age.

The medicines affected by this communication are those listed below:

- Risperdal 1 mg/ml oral solution (JANSSEN-CILAG SPA)
- Risperidone Aurobindo Pharma Italia 1 mg/ml oral solution (AUROBINDO PHARMA (ITALIA) S.R.L.)
- Risperidone Mylan Generics 1 mg/ml oral solution (MYLAN S.P.A.)
- Risperidone Sandoz GmbH 1 mg/ml oral solution (SANDOZ GMBH)

Further information:

- Risperidone is a substance with antipsychotic action that at the paediatric level is indicated for the short-term (up to 6 weeks) treatment of persistent aggression in intellectually disabled children (aged 5 years or older) and adolescents with conduct disorder. Pharmacological

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treatment should be an integral part of a more complete therapeutic programme preferably under the supervision of a specialist in paediatric neurology and child and adolescent psychiatry, or by physicians experienced in the treatment of conduct disorder in children and adolescents.

- In children over 5 years of age, the dose is determined differently for children and adolescents with a body weight <50 kg or ≥50 kg. In children weighing less than 50 kg, oral solution is the formulation to be used, while in older children and adolescents (≥50 kg) tablets or oral solution may be used. Neither the product nor the device is approved for weight-based dosing in milligrams per kilogram.
- Administration should be carried out using the dosing syringe included in the medicine package.

Call for reporting:

If you observe any adverse events associated with medicines, please report them through the national pharmacovigilance system. More information can be found on AIFA's institutional website at the following link: http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse.

AIFA takes this opportunity to remind healthcare professionals and patients/citizens of the importance of reporting adverse drug reactions as an indispensable tool for confirming the favourable benefit/risk ratio in real conditions of use.

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