Direct Healthcare Professional Communication

May 2024

Risperidone oral solution formulation-Risk of accidental overdose following administration errors

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you **about risk of accidental overdose following administration errors.**

Summary:

- The Egyptian Drug Authority (EDA) received cases of accidental overdose due to administration errors of medicines containing risperidone, in oral solution formulation, in children and adolescents
- The Egyptian Drug Authority (EDA) 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 pediatric and adolescent patients.
- 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.
- It is recommended that prescribing physicians and pharmacists carefully instruct parents and/or carers on how to measure the exact dose to be administered and ensure that they understand it correctly.
- In case of any doubt about the use of the medicine, parents and/or carers should consult their doctor or pharmacist.
- Medicines containing risperidone are not indicated for use in children under 5 years of age

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 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.

Paediatric population from 5 to 18 years of age

For subjects > 50 kg, a starting dose of 0.5 mg once daily is recommended. This dosage can be individually adjusted by increments of 0.5 mg once daily not more frequently than every other day, if needed. The optimum dose is 1 mg once daily for most patients. Some patients, however, may benefit from 0.5 mg once daily while others may require 1.5 mg once daily.

For subjects < 50 kg, a starting dose of 0.25 mg once daily is recommended. This dosage can be individually adjusted by increments of 0.25 mg once daily not more frequently than every other day, if needed. The optimum dose is 0.5 mg once daily for most patients. Some patients, however, may benefit from 0.25 mg once daily while others may require 0.75 mg once daily.

Administration should be carried out using the graduated dropper included in the medicine package.

Reference:

Italy:
https://www.aifa.gov.it/documents/20142/1135360/Comunicazione-AIFA-Risperidone_03.05.2024_EN.pdf

MHRA:https://mhraproducts4853.blob.core.windows.net/docs/ba9925c77b3f48bb6fbde11b5c3c6c0bd06e0e55

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301