Direct Healthcare Professional Communication

May 2022

Injectable Trimebutine- Risk of Cardiac Toxicity in the Event of Misuse

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

- The off-label use of trimebutine by injection is of concern with regard to its cardiac toxicity.
- A serious case of cardiorespiratory arrest has been reported in a 66-year-old patient who received multiple direct central line intravenous injections of high doses of trimebutine maleate (100 mg, 3 times daily) to treat ileus following surgery for adenocarcinoma.
- This use is no longer part of the marketing authorization indications since 2017, following a reassessment of the benefit/risk ratio (no well conducted clinical study has provided proof of the efficacy of trimebutine in paralytic ileus).

Background on the safety concern

In October 2021, a survey was carried out to assess the practices associated with the use of the injectable form of trimebutine. Thus, among the 133 health institutions located in 19 departments that responded to the survey, 99 mentioned the use of injectable trimebutine with:

- non-compliance with the MA indication in approximately 48% of institutions (in particular, off-label use in postoperative paralytic ileus and use in endoscopic examinations).
- non-compliance with the dosage, with high dosages (> 200 mg) in approximately 35% of institutions and very high dosages (> 400 mg) in approximately 12% of institutions.

Injectable trimebutine is reserved for the symptomatic treatment of pain, transit disorders and intestinal discomfort related to functional intestinal disorders, when the use of the oral route is not possible,

Its dosage is one intramuscular (IM) or intravenous (IV) injection of one ampoule (50 mg/5 ml) during the acute phase of intestinal disorders.

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References

France

https://ansm.sante.fr/uploads/2022/04/06/20220406-dhpc-debridat.pdf

Call for reporting

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

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 – 23610497

Email: pv.followup@edaegypt.gov.eg

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

Hotline: 15301

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