Direct Healthcare Professional Communication

Sep 2023

Pholcodine - The use of pholcodine in the 12 months before general anesthesia with neuromuscular blocking agents (NMBA) is a risk factor for developing an anaphylactic reaction (a sudden, severe and life-threatening allergic reaction) to NMBAs

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 of the following **risk of developing an anaphylactic reaction (a sudden, severe and life-threatening allergic reaction) to NMBAs**:

Summary:

- Use of pholcodine within 12 months preceding anesthesia with neuromuscular blocking agents (NMBAs) has been linked to a risk of peri anesthetic anaphylactic reaction to NMBAs.
- No effective measures have been identified to minimize this risk in patients exposed to pholcodine-containing medicinal products.
- Doctors should re-evaluate their patients, consider other treatment alternatives, and advise patients to stop using pholcodine-containing medicinal products.
- In case of anaesthesia requiring administration of NMBAs, healthcare professionals should check whether patients have used pholcodine-containing medicinal products in the last 12 months and if so, maintain awareness of potential perianaesthetic anaphylactic reactions to NMBAs.

Further Information:

Pholcodine monohydrate is a cough suppressant with mild sedative but little analgesic action. Its depressant effects on the respiration are less than those of morphine. It has been suggested that it produces its major effect on the patient's subjective reactions to the cough, rather than on the frequency and intensity of coughing.

Opioids act as agonists, interacting with stereospecific and saturable binding sites or receptors in the brain and other tissues.

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Pholcodine-containing medicinal products have been the subject of two EU safety reviews in 2011 and in 2022 regarding the potential risk that pholcodine may lead to IgE-sensitisation to neuromuscular blocking agents (NMBAs) and to anaphylactic reactions as a result.

In 2011, the safety review concluded that the benefit-risk balance of pholcodine-containing medicinal products in the treatment of non-productive cough was positive under normal conditions of use.

However, it was concluded that the possibility of an association between pholcodine use and a perianaesthetic anaphylactic reaction to NMBAs should be further investigated. Therefore, a postauthorisation safety study (PASS) was imposed.

In 2022, the final results of the PASS, called ALPHO, became available showing a link between use of pholcodine within 12 months preceding anaesthesia with NMBAs and a risk of perianesthetic anaphylactic reaction related to NMBAs.

References:

***EMA**: https://www.ema.europa.eu/en/documents/referral/pholcodine-medicines-withdrawn-eu-market_en.pdf*

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

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