Direct Healthcare Professional Communication

November 2025

Risk of Seizures in Breastfed Infants Due to Mothers' Use of Dicyclomine/Dicycloverine-Containing Products

Dear Healthcare Professional,

In line with the recommendations from the Pharmaceutical Vigilance Committee regarding a potential safety signal of infant seizures linked to the use of dicyclomine/dicycloverine-containing products by breastfeeding mothers, the Pharmaceutical Vigilance General Administration (PVGA) at the Egyptian Drug Authority (EDA) wishes to inform internal medicine physicians, pediatric specialists, and other healthcare professionals involved in the care of breastfeeding women treated for maldigestion-related conditions.

Summary

A review of three reported cases involving infants aged 4 to 12 months who developed seizures following maternal use of dicyclomine/dicycloverine-containing products during breastfeeding was conducted, and the following was concluded:

- All cases were serious with positive de-challenge.
- Evaluation of the available evidence, including literature findings, indicates a possible causal link, as dicyclomine/dicycloverine can be excreted into breast milk and reach the infant.
- Additionally, there are reports that administration of dicyclomine hydrochloride/dicycloverine syrup to infants has been followed by serious respiratory symptoms (dyspnea, shortness of breath, breathlessness, respiratory collapse, apnea, asphyxia), seizures, syncope, pulse rate fluctuations, muscular hypotonia, coma, and death (1).
- No causal relationship has been established between the observed effects in infants and the administration of dicyclomine/dicycloverine.
- Dicyclomine/Dicycloverine is contraindicated in infants less than 6 months of age and in nursing mothers, as mentioned in the FDA dicyclomine/dicycloverine-containing products label (2).

Recommendations for Healthcare Professionals

Healthcare professionals are advised to educate patients, especially nursing mothers, about the following:

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- Potential neurological disorders, including seizures in infants, are associated with the administration of dicyclomine/dicycloverine-containing products by the mothers, as dicyclomine/dicycloverine can pass to infants through breast milk.
- Dicyclomine/Dicycloverine is contraindicated in infants less than 6 months of age and in nursing mothers.
- Report any adverse drug reactions related to dicyclomine/dicycloverine-containing products to the Pharmaceutical Vigilance General Administration (PVGA), Egyptian Drug Authority.

Background

Dicyclomine/Dicycloverine is a muscarinic M1, M3, and M2 receptor antagonist as well as a non-competitive inhibitor of histamine and bradykinin used to treat spasms of the intestines seen in functional bowel disorder and irritable bowel syndrome. Though it is commonly prescribed, its recommendation may have been based on a small amount of evidence, and so its prescription is becoming less favorable. Patients experiencing an overdose may present with headache, nausea, vomiting, blurred vision, dilated pupils, dizziness, dry mouth, difficulty swallowing, CNS stimulation, as well as hot, dry skin. Management of overdose toxicity includes gastric lavage, emetics, activated charcoal, sedatives for excitement, and a cholinergic agent if indicated (3).

Seizures involve uncontrolled, abnormal electrical activity in the brain that can alter consciousness, behavior, memory, or sensations. The differential diagnosis includes conditions such as convulsive concussion, syncope, movement disorders, rigors, sleep-related events, and psychogenic non-epileptic episodes. Seizures are classified as partial, originating in a specific cortical area and often presenting with focal motor or sensory symptoms, or generalized, which involve widespread cortical activation from the onset or spread of partial activity (4).

References

1. Aziz NA, Teja MB, Hassan Y, Rujhan MR, Jaalam K. Low Dose of Dicyclomine Associated with Respiratory Distress and Death in an Infant. Journal of Pharmacy Technology. 1999 Mar 1;15(2):56–8.
2. Dicyclomine Hydrochloride [Internet]. [cited 2025 Nov 17]. Available from: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=57ab6992-7b98-4503-b4bb-98d76ccf603e&type=display
3. Dicyclomine [Internet]. [cited 2025 Nov 17]. Available from: https://go.drugbank.com/drugs/DB00804
4. Lovik K, Murr NI. Seizure. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 [cited 2025 Nov 17]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK430765/

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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://vigiflow-eforms.who-umc.org/eg/med

QR Code:

Hotline: 15301

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