Direct Healthcare Professional Communication

July 2026

Domperidone-containing drugs: New contraindication for patients with suspected or confirmed pheochromocytoma

Dear Healthcare Professional,

[Marketing Authorization Holder (MAH) Name], in agreement with the General Administration for Pharmaceutical Vigilance (PVGA) of the Central Administration for Pharmaceutical Care at the Egyptian Drug Authority (EDA), would like to inform you of the following important safety update:

Summary

- **Risk Identified:** A risk of severe hypertensive episodes has been identified in patients with suspected or confirmed pheochromocytoma when taking domperidone-containing medications.
- **Summary of Product Characteristics (SmPC) Update:** The **"Contraindications"** section is being updated to include: *"Suspected or confirmed pheochromocytoma due to the risk of severe hypertensive episodes."*
- **Patient Information Leaflet (PIL) Update:** The section **"When should you not take/use this medication?"** is being updated to include: *"If you have or might have a rare tumor of the adrenal gland (pheochromocytoma), as this medication could cause a severe rise in your blood pressure."*

Background

Domperidone is a D2 antagonist with antiemetic properties. It is only partially crosses the blood-brain barrier. Its antiemetic effect is presumably based on a combination of peripheral (gastrokinetic) effects and D2 receptor antagonism in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema.

Animal studies and the low concentrations of domperidone in the brain suggest a predominantly peripheral effect of domperidone at the D2 receptors.

Domperidone is approved for the relief of nausea and vomiting.

Pheochromocytoma is a neuroendocrine tumor that arises predominantly from the chromaffin cells of the adrenal medulla and is characterized by autonomous and excessive secretion of catecholamines. This excessive hormone release can lead to persistent or paroxysmal hypertension, tachyarrhythmias, metabolic disturbances, and acute hypertensive crises with potentially life-threatening cardiovascular complications.

A causal relationship between domperidone and acute episodes of hypertension in patients with pheochromocytoma is considered at least possible.

This safety evaluation was triggered by a published case report and supported by spontaneous adverse event data showing positive dechallenge and rechallenge for paroxysmal hypertension within ~2 hours of administration. Following surgical resection of the pheochromocytoma, re-administration of domperidone did not produce any rise in blood pressure.

Two plausible mechanisms are proposed:

- **Dopaminergic Blockade in Adrenal Medulla:** Blocking dopamine D2 receptors in the adrenal gland can trigger sudden exocytosis of massive amounts of stored catecholamines into the circulation. While well-documented for metoclopramide, a similar mechanism applies to domperidone.
- **Gastrointestinal Motility Stimulation:** Domperidone antagonizes the inhibitory effects of dopamine on GI smooth muscle, driving increased motility. In the presence of a pheochromocytoma, this sudden mechanical/autonomic stimulation may induce abnormal catecholamine release.

Recommendations for Healthcare Professionals

- **Check Patient History:** Do not prescribe or administer domperidone-containing medications to patients with known or suspected pheochromocytoma.
- **Monitor High-Risk Patients:** Exercise caution and evaluate underlying conditions in patients presenting with unexplained paroxysmal hypertension following prokinetic administration.
- **Adverse Event Reporting:** Please report any suspected adverse reactions associated with **domperidone-containing products** to the General Administration for Pharmaceutical Vigilance (GAPV) at the Egyptian Drug Authority (EDA).

References

Swiss medic :

https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/health-professional-communication--hpc-/dhpc-domperidon-domperidon.html

Call for reporting

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

Name: General Administration for Pharmaceutical Vigilance

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt,

Email: pv.followup@edaegypt.gov.eg
Online reporting: : https://vigiflow-eforms.who-umc.org/eg/med
QR Code:

Hotline: 15301