COMMUNICATION

COM-2025-037

26 JUNE 2025

URGENT PLEASE REVIEW

# Safety Notification

PharmPix Clinical Department


PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

## U.S. Food & Drug Administration Publication Date:

06/18/2025

## Drug Indication:

To prevent nausea and vomiting associated with motion sickness.

## Safety Topic:

FDA adds warning about serious risk of heat-related complications with antinausea patch Transderm Scōp (scopolamine transdermal system).

## FDA Adds Warning about Serious Risk of Heat-Related Complications with Transderm Scōp

It is for this reason that we are notifying you that on 06/18/2025 the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Transderm Scōp (scopolamine transdermal system).

### Reason for Communication:

The FDA is warning that the antinausea patch Transderm Scōp (scopolamine transdermal system) can increase body temperature and cause heat-related complications, resulting in hospitalization or even death in some cases. Most cases occurred in children 17 years and younger and in adults 60 years and older, who may be sensitive to body temperature control disturbances. As a result, the FDA required that the Transderm Scōp prescribing information be revised to include a warning and other information about this risk.

Most reports of hyperthermia that resulted in serious harm occurred when the Transderm Scōp was used in children 17 years and younger. Hyperthermia occurred most often within 72 hours after the Transderm Scōp patch was applied to patients' bodies for the first time. Hyperthermia may be exacerbated when patients are in warm environmental temperatures and when they are using external heat sources, such as a heated blanket.

### Pharmacy Required Action:

Advise patients that if they experience hyperthermia symptoms to remove the patch and contact their health care professional. Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

1. U.S. Food and Drug Administration (2025). *FDA adds warning about serious risk of heat-related complications with antinausea patch Transderm Scōp (scopolamine transdermal system)* https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-warning-about-serious-risk-heat-related-complications-antinausea-patch-transderm-scop


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