

Transderm[®] Scōp (scopolamine transdermal system) – Drug safety communication

- On June 18, 2025, the [FDA warned](#) 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.
 - Prescribing information has been revised to include a warning and other information about this risk.
- Transderm Scōp is approved in adults for the prevention of:
 - Nausea and vomiting associated with motion sickness
 - Post-operative nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery.
- The Transderm Scōp patch is not approved for any use in children; however, it is sometimes prescribed off-label for this population. For example, it has been used off-label to manage excessive drooling in children with cerebral palsy or other neurologic disorders.
- Through August 16, 2024, the FDA identified 13 cases worldwide, including 7 in the U.S., of hyperthermia associated with scopolamine patches from the FDA Adverse Event Reporting System (FAERS) database, biomedical literature, manufacturer-submitted data, or an external regulatory body.
 - Of the 13 cases, 8 involved children 17 years or younger, 4 involved adults 60 years and older, and the remaining patient was a young adult.
 - Among the 13 cases, most (n = 12) had a serious outcome, with 6 cases resulting in hospitalization (n = 4) or death (n = 2).
 - The deaths occurred in 1 child and 1 older adult patient; both cases had other risk factors that may have contributed to the development of hyperthermia, such as receiving a concomitant medication with anticholinergic activity or exposure to an external heat source.
- Hyperthermia occurred most often within 72 hours after the Transderm Scōp patch was applied to patients' bodies for the first time. The Transderm Scōp patch can affect the body's ability to maintain a stable internal temperature, leading to a rise in core body temperature. It can also reduce sweating, which may cause increases in body temperature. Severe cases may lead to heat-related complications, such as confusion, loss of consciousness, coma, or death. Hyperthermia may be exacerbated when patients are in warm environmental temperatures and when they are using external heat sources, such as a heated blanket.
- Healthcare professionals should discuss the risk of hyperthermia and associated serious harms with patients when prescribing the Transderm Scōp patch, especially in children and older adult patients.
- Patients should remove the Transderm Scōp patch from their skin if they develop symptoms of hyperthermia, including increased body temperature or reduced sweating in warm environmental

- temperatures, and should contact their health care professional. Hyperthermia symptoms may persist following removal of the Transderm Scōp patch because of continued presence of the absorbed medicine in the body.



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