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IN BRIEF

Hyperthermia with Scopolamine Patches

The FDA has required a new warning in the label for the scopolamine transdermal patch (*Transderm-Scōp*, and generics) about a risk of serious or fatal hyperthermia. Scopolamine, an anticholinergic drug, is FDA-approved for prevention of nausea and vomiting associated with motion sickness or recovery after surgery in adults; it is often used off-label to reduce drooling in children and adolescents with neurologic disorders.

An FDA review identified 13 cases of hyperthermia associated with use of the scopolamine patch, including 8 cases in children ≤ 17 years old and 4 in adults ≥ 60 years old. Hyperthermia typically began within 72 hours after application of a patch and was usually accompanied by other symptoms of toxicity, such as mydriasis, disorientation, or urinary retention. Most cases occurred after the first application, but one occurred 18 months after treatment initiation. Some cases involved use of patches that had been cut or application of multiple patches at the same time. Four cases resulted in hospitalization, and body temperature peaked at $\geq 105^{\circ}\text{F}$ in 3 of 10 cases with available data. One child and one older adult died; both patients had other risk factors such as use of another drug with anticholinergic effects or exposure to an external heat source.¹

The updated label advises clinicians to counsel patients about the risk of hyperthermia with use of the scopolamine patch. Patients should apply only one patch at a time and should not cut the patches. Those who experience an increase in body temperature or a lack of perspiration in warm conditions should remove the patch and contact a healthcare provider. ■

1. FDA Drug Safety Communication. FDA adds warning about serious risk of heat-related complications with antinausea patch Transderm Scōp (scopolamine transdermal system). June 18, 2025. Available at: <https://bit.ly/4lJFxTW>. Accessed July 30, 2025.

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