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

June 18, 2025 FDA Drug Safety Communication

What safety concern is FDA announcing?
The U.S. Food and Drug Administration (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, we 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. Transderm Scōp is not FDA-approved for any use in children but is sometimes prescribed "off-label" (which means that it is not an FDA-approved use) to manage excessive drooling in children with cerebral palsy or other neurologic disorders.

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.

What is FDA doing?
We required the addition of a new warning and other information to the Transderm Scōp prescribing information and patient information leaflet about the risk of hyperthermia resulting in serious harm. These revisions include information to help reduce this risk, particularly in children and older adult patients. It instructs patients to remove the Transderm Scōp patch if their body temperature increases or if they are not sweating in warm environmental temperatures and to contact their health care professional if they are experiencing symptoms.

What is the Transderm Scōp patch and how can it help me?
Transderm Scōp (scopolamine transdermal system) is a prescription medicine, available as a patch, that FDA approved for adults in 1979 to prevent nausea and vomiting associated with motion sickness. FDA later also approved it for adults to prevent nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery. The Transderm Scōp patch releases a medicine called scopolamine, an anticholinergic agent that blocks signals from a brain substance that causes nausea and vomiting. The Transderm Scōp patch is applied behind the ear

and delivers the medicine for up to 3 days. Scopolamine patches are also available as generic products.

Although the Transderm Scōp patch is not approved for any use in children, 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.

What should patients and parents/caregivers do?
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.

Be aware that hyperthermia symptoms may persist after removing the Transderm Scōp patch because the absorbed medicine will remain in the body for a period of hours to days. When using the Transderm Scōp patch, avoid using external heat sources, such as heated blankets. Transderm Scōp is not approved for long-term use or in children, so parents and caregivers should discuss the benefits and risks with their health care professional, who can provide advice and information based on individual needs.

What should health care professionals do?
Discuss the risk of hyperthermia and associated serious harms with patients when prescribing the Transderm Scōp patch, especially in children and older adult patients who may be more susceptible to the anticholinergic effects of thermoregulatory disruption. Instruct patients to remove the patch and to contact their health care professional if they experience hyperthermia symptoms, including increased body temperature or reduced sweating in warm environmental temperatures.

Make patients aware that after they remove the Transderm Scōp patch, symptoms of hyperthermia may persist because the absorbed medicine will remain in the body for a period of hours to days.

What did FDA find?
FDA identified 13 cases worldwide, including 7 in the United States, of hyperthermia associated with scopolamine patches received by FDA* through August 16, 2024 (see Data Summary). We determined there is reasonable evidence of a causal association between the scopolamine patches and hyperthermia based on how the medicine works, including its ability to cross the blood-brain barrier, a membrane that prevents potentially harmful substances in the blood from reaching the brain. In addition, hyperthermia may be associated with "anticholinergic syndrome," which is a group of symptoms resulting from high exposure to anticholinergic agents and can include dry mouth, blurred vision, and dilated pupils. Of the reported cases, 8 were in children 17 years and younger, and 4 were in adults 60 years and older; these groups may be sensitive to body temperature control disturbances. Four of the 13 cases resulted in hospitalization and 2 in death. The deaths occurred in 1 child and 1 older adult patient. The time from application of the scopolamine patch to hyperthermia onset was typically less than 72 hours.

*The cases were identified from the FDA Adverse Event Reporting System (FAERS) database, biomedical literature, manufacturer-submitted data, or external regulatory body; additional cases may exist.

What is my risk?
All medicines have a risk of side effects even when used correctly as prescribed. People respond differently to medicines depending on their health, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine how likely it is that someone will experience hyperthermia when using Transderm Scōp (scopolamine transdermal system). Talk to your health care professionals if you have questions or concerns about the risks of using this medicine.

How do I report side effects from Transderm Scōp (scopolamine transdermal system)?
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving the Transderm Scōp patch or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

How can I get new safety information on medicines I'm prescribing or taking?
You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Facts about Transderm Scōp (scopolamine transdermal system)

- The Transderm Scōp patch is a prescription medicine that is FDA-approved in adults to prevent nausea and vomiting associated with motion sickness and to prevent post-operative nausea and vomiting associated with recovery from anesthesia or opioid pain medicines used during surgery. It is not FDA-approved for use in children 17 years or younger.
- The Transderm Scōp patch releases scopolamine, an anticholinergic agent that blocks signals from a brain substance called acetylcholine that causes nausea and vomiting.
- The Transderm Scōp patch is applied to the skin behind the ear and delivers the medicine for up to 3 days.
- Only wear 1 Transderm Scōp patch at a time.
- Do not cut the Transderm Scōp patch.
- Common side effects of the Transderm Scōp patch include dry mouth, drowsiness, dizziness, sore throat, and trouble seeing.
- In 2023, an estimated 1.73 million prescriptions for scopolamine patches were dispensed from U.S. outpatient pharmacies. Approximately 3 percent (n=54,600) of those prescriptions were dispensed for pediatric patients 17 years and younger, mostly (n=46,100) for patients 9-17 years old.[1]

Additional Information for Patients and Caregivers

- FDA is warning that the antinausea patch Transderm Scōp (scopolamine transdermal system) can lead to an increase in body temperature, resulting in hospitalization or death in some instances from heat-related complications.
- 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.
- The time from application of the Transderm Scōp patch to the skin for the first time to the start of hyperthermia was typically less than 72 hours.
- We required the addition of a new warning and other information about the risk of hyperthermia to the prescribing information and patient information leaflet for the Transderm Scōp patch.
- Remove the Transderm Scōp patch and contact your health care professional if your body temperature increases or if you are not sweating in warm environmental temperatures.
- Be aware that hyperthermia symptoms may persist after removing the Transderm Scōp patch because of continued presence of the absorbed medicine in the body.
- To help FDA track safety issues with medicines, report side effects from the Transderm Scōp patch or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Additional Information for Health Care Professionals

- FDA is warning about the risk of hyperthermia with Transderm Scōp (scopolamine transdermal system), approved in adults to prevent nausea and vomiting associated with motion sickness and to prevent post-operative nausea and vomiting associated with recovery from anesthesia or opioid pain medicines used during surgery.
- This risk has been associated with serious outcomes, including hospitalization and death.
- The time from application of the Transderm Scōp patch to onset of hyperthermia was typically less than 72 hours.
- We required the addition of the risk of hyperthermia resulting in serious harm to the *Warnings and Precautions* section of the prescribing information for the Transderm Scōp patch. Changes were also made to additional sections of the prescribing information, including *Pediatric Use, Geriatric Use*, *Overdosage,* and the *Patient Counseling Information*, as well as to the patient information leaflet.
- Discuss the risk of hyperthermia and associated serious outcomes with patients when prescribing the Transderm Scōp patch, especially in children and older adult patients who may be susceptible to the anticholinergic effects of thermoregulatory disruption.
- Inform patients that the Transderm Scōp patch can increase body temperature and reduce sweating, which may result in hyperthermia and be exacerbated by exposure to external heat sources (e.g., heated blankets) or high environmental temperatures.
- Instruct patients if they experience hyperthermia symptoms, including if their body temperature increases or if they are not sweating in warm environmental temperatures, to remove the Transderm Scōp patch and contact their health care professional.

- Make patients aware that hyperthermia symptoms may persist following removal of the Transderm Scōp patch because of continued presence of the absorbed medicine in the body.
- To help FDA track safety issues with medicines, report side effects from the Transderm Scōp patch or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
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Data Summary

Through August 16, 2024, FDA identified 13 cases worldwide, including 7 in the United States, of hyperthermia associated with scopolamine patches from the FDA Adverse Event Reporting System (FAERS) database, biomedical literature, manufacturer-submitted data, or external regulatory body. Among the 10 cases that provided information on body temperature, 3 reported maximum body temperatures of 105°F or higher; the remaining 7 had maximum body temperatures of 99 to 100.4°F (n=2) or 100.5 to 104.9°F (n=5). Among the 8 cases reporting the time interval between scopolamine patch application and the onset of hyperthermia, all occurred 72 hours or less after the most recent application; notably, 7 of these cases occurred after initial application of the patch to the patient's body, and 1 occurred 18 months after treatment initiation. One case described applying multiple scopolamine patches simultaneously, and another described applying a scopolamine patch that had been cut.

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. The reported reasons for using the scopolamine patch were to manage drooling/secretions (n=6) or motion sickness/nausea (n=4); the remaining 3 cases did not report a reason for use. The majority of cases (n=10) described at least 1 other anticholinergic symptom in addition to hyperthermia, such as mydriasis (pupil dilation), hallucinations, confusion, disorientation, or urinary retention.

Reference

1. Symphony Health, an ICON plc company, Metys® database. Study period: 2018-2023. Data extracted September 2024. Data were obtained from a proprietary data source under a contract with FDA.

Related Information

- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines