

Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-013-CG **July 2, 2025**

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. 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.

RECOMMENDATIONS

1. **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.
- 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.

2. **Health Care Professionals**

- 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.
3. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

Transderm Scōp (Scopolamine Transdermal System): Drug Safety Communication - FDA Adds Warning About Serious Risk of Heat-Related Complications with Antinausea Patch

The patch can increase body temperature and cause heat-related complications, resulting in hospitalization or even death in some cases

AUDIENCE: Patient, Health Care Professional, Neurology

ISSUE: 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. 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.

BACKGROUND: 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 or opioid pain medicines used during 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.

RECOMMENDATIONS:

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.
- 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.

Health Care Professionals

- 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.