

DRUG SAFETY NOTICE

Safety Update

DRUG NAME/STRENGTH/FORM:

Hyoscine hydrobromide patches (Scopoderm 1.5mg Patch or Scopoderm TTS Patch): risk of anticholinergic side effects, including hyperthermia.

PROBLEM

There have been a small number of reports of serious and life-threatening anticholinergic side effects associated with hyoscine hydrobromide patches, particularly when used outside the licence. Healthcare professionals, patients, parents, and carers should be aware of the signs and symptoms of serious side effects and the need to seek medical help if they occur.

The licensed indication of a hyoscine hydrobromide patch ([Scopoderm 1.5 mg Patch](#)) is for the prevention of motion or travel sickness symptoms (for example nausea, vomiting and vertigo) in adults and children aged 10 years of age or older. Each patch should be used for 72 hours.

There is widespread use of hyoscine hydrobromide patches outside the licence. Usage outside the licence includes:

- indications other than motion or travel sickness
- use in children younger than 10 years of age.
- cutting patches (this may adversely affect the bioavailability of the drug)
- application of more than one patch at a time
- continuous use without a break/long-term use
- the management of hypersecretion or hypersalivation in diverse clinical populations; for example,
 - in patients with complex multiple disabilities or cerebral palsy,
 - patients on ventilation, patients with Parkinson's disease,
 - patients requiring palliative care, and patients with drug-induced hypersalivation

ADVICE - For Healthcare Professionals

Be alert to the potential for anticholinergic side effects in patients who are prescribed hyoscine hydrobromide patches, particularly if used outside the licence.

- Children and elderly patients are more susceptible to anticholinergic toxicity.
- Serious anticholinergic side effects can include hyperthermia, urinary retention, delirium, hallucinations, seizures, coma, and respiratory paralysis.
- If used in hospital or residential care settings, monitor patients for signs and symptoms of anticholinergic side effects and manage these promptly if they occur.

- If used at home, counsel patients, parents and carers on side effects to be aware of and what to do if they occur.
- Report suspected adverse drug reactions associated with hyoscine hydrobromide to the [Yellow Card scheme](#).

ADVICE - To counsel patients, parents and carers.

- Hyoscine hydrobromide patches are used commonly without any problems.
- All medicines can cause unwanted side effects, and while not everybody gets them, some side effects can be serious and even life-threatening.
- It is important to be aware of the signs and symptoms of serious side effects that could be associated with hyoscine hydrobromide patches – these include high temperature, inability to urinate, confusion, disorientation, seeing or hearing things that are not there, fits or convulsions, reduced consciousness, and breathing difficulties.
- If these symptoms occur seek medical help and remove the patch immediately
- If there is a high temperature, take immediate action to reduce body heat in addition to seeking medical help and removing the patch.

ACTIONS

- Be aware of the risk of anticholinergic side effects
- Counsel patients and their parent/guardians/carers on the signs and symptoms of anticholinergic side effects

Report any suspected adverse drug reactions (ADRs) to hyoscine hydrobromide patches via the [Yellow Card scheme, encourage patients and their parent/guardians/carers to report](#).

KEY DOCUMENTS

BNF – Hyoscine Hydrobromide	SmPC - Scopoderm 1.5mg Patch	Yellow Card website
BNFC – Hyoscine Hydrobromide		
Hyoscine hydrobromide patches to reduce saliva production		

FOR FURTHER INFORMATION CONTACT YOUR WARD BASED PHARMACY TEAM

OR

THE PHARMACY DEPARTEMENT (CITY ext.5263; SANDWELL ext.3783).

OUT OF HOURS CONTACT THE ON-CALL PHARAMCIST

DATE OF ISSUE: 03/04/2024

REFERENCE NUMBER: 01-0424