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(IN REPLY PLEASE QUOTE THIS FILE REF.)

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Dear Healthcare Professionals,

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

Your attention is drawn to the United Kingdom Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that 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.

In the United Kingdom, the licensed indication of a hyoscine hydrobromide patch (Scopoderm 1.5mg Patch or Scopoderm TTS 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. Hyoscine hydrobromide patches are often recommended in clinical guidance for indications other than motion or travel sickness.

Hyoscine hydrobromide is a muscarinic acetylcholine receptor antagonist. Since it crosses the blood-brain barrier it has both central and peripheral actions, causing a range of anticholinergic side effects including hyperthermia, urinary retention, dry mouth, disturbances of visual accommodation (blurred vision), mydriasis, skin irritation, generalised rash, somnolence, dizziness, memory impairment, disturbances in attention, restlessness, disorientation, confusion, hallucinations, delirium, seizures, coma, and respiratory paralysis.

After removal of the patch, hyoscine in the skin continues to enter the blood stream. Side effects may therefore persist for up to 24 hours or longer after patch removal. Children and elderly people are more susceptible to anticholinergic toxicity. Other specific risk factors for developing side effects have not been identified and there is no robust data available to give an estimate of frequency.

Hyoscine hydrobromide patches are used widely, however there have been a small number of serious and life-threatening anticholinergic side effects reported, particularly in use outside the licence. This includes the unexpected death of a child from hyperthermia caused by the hyoscine hydrobromide patch.

Following advice from the Paediatric Medicines Expert Advisory Group (PMEAG) of the Commission on Human Medicines, MHRA has requested that Marketing Authorisation Holders (MAHs) for hyoscine hydrobromide patches add hyperthermia to both the list of side effects in section 4.8 (undesirable effects) of the Summary of Product Characteristic (SmPC) and to the Patient Information Leaflet (PIL). This is consistent with current warnings in the tablet formulation. MHRA has also requested that the MAHs include information in the PIL regarding actions to take if hyperthermia occurs. This is consistent with information in Section 4.9 (overdose) of the SmPC. The PMEAG also noted that underreporting of anticholinergic side effects is likely and encouraged the reporting of adverse reactions through the Yellow Card scheme.

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.
- Usage outside the licence includes: use for indications other than motion or travel sickness, use in children younger than 10 years of age, cutting patches, application of more than one patch at a time, continuous use of patches without a break, and long-term use.
- 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.

Please refer to the following website in MHRA for details:
https://www.gov.uk/drug-safety-update/hyoscine-hydrobromide-patches-scopoderm-1-dot-5mg-patch-or-scopoderm-tts-patch-risk-of-anticholinergic-side-effects-including-hyperthermia

In Hong Kong, there are 2 registered pharmaceutical products which are transdermal patches containing hyoscine. These products are pharmacy only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction related to hyoscine, but these cases were not related to anticholinergic side effects including hyperthermia. In light of the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Terence MAN)
for Assistant Director (Drug)