

28th April 2010

Direct Healthcare Professional Communication on the inappropriate use of and medication errors associated with Exelon[®]/ Prometax[®] transdermal patch .

Dear Doctor,

Novartis, in agreement with EMA and the IMB, would like to remind Healthcare Professionals of the importance of the proper use and application of Exelon[®]/ Prometax[®]¹ transdermal patch (rivastigmine transdermal patch).

Key messages

- Medication errors and inappropriate use of Exelon[®]/ Prometax[®] transdermal patch have been reported, some of these resulting in rivastigmine overdose. Symptoms of overdose include nausea, vomiting, diarrhoea, hypertension, and hallucinations.
- The most frequent reported causes are lack of patch removal and application of more than one patch at the same time.
- It is important for healthcare professionals to instruct patients and caregivers on the proper use of the transdermal patch and particularly that :
 - only one transdermal patch should be applied per day to healthy skin on one of the recommended locations: the upper or lower back, or upper arm or chest
 - The patch should be replaced by a new one after 24 hours, and the previous day's patch must be removed before applying a new patch to a different skin location;
 - To minimize skin irritation, application to the same skin location within 14 days should be avoided.
 - The transdermal patch should not be cut into pieces.

Further information on medication errors and inappropriate use

Post-marketing reports of medication errors and inappropriate use have been received with Exelon[®]/Prometax[®] transdermal patch. The most common errors reported were drug administration error, wrong technique in drug usage process, and incorrect dose administered. The most frequent reported causes are lack of patch removal and application of more than one patch at the same time. Other common errors are

¹ ¹ In the European Union, Exelon[®]/Prometax[®] transdermal patch is indicated for the symptomatic treatment of mild to moderately severe Alzheimer's dementia. Exelon[®]/ Prometax[®] transdermal patch is available in two dosage strengths 4.6 mg /24 hours and 9.5 mg /24 hours. Treatment is started with 4.6 mg /24h. After a minimum of four weeks and if well tolerated according to the treating physicians, the daily dose is should be increased to 9.5 mg /24h which is the recommended effective dose

application on non-recommended sites or on the same area for several weeks, cutting the patch into several pieces, and error of dosages (prescription / dispensation). Healthcare professionals, caregivers, or the patients themselves have been involved in these errors.

Overdose with rivastigmine resulting from medication errors and inappropriate use of Exelon®/ Prometax® transdermal patch (e.g. application of multiple patches at a time) has been reported. The typical symptoms reported in association with overdose include nausea, vomiting, diarrhoea, hypertension, and hallucinations. Bradycardia and/or syncope, that may be associated with malaise or falls, may also occur. As with medication errors and misuse in general, serious medical outcomes, possibly including death, may occur if the medication errors and misuse are not corrected in a timely manner and properly managed. In case of overdose, all Exelon®/Prometax® patches should be immediately removed. Please refer to section 4.9 of the Summary of Product Characteristics (section on Overdose) in the attached prescribing and patient information for additional details concerning the proper management of overdose related to Exelon®/Prometax® transdermal patch.

Further information on recommendations to healthcare professionals

Healthcare professionals should be well informed on the proper use and administration of Exelon®/Prometax® transdermal patch as described in the Summary of Product Characteristics (SmPC) and must follow the instructions on “HOW TO USE EXELON” as described in Section 3 of the attached Package Leaflet. Physicians should advise patients and caregivers accordingly prior to initiating therapy with Exelon®/Prometax® transdermal patch. Therapy with rivastigmine should only be started if a caregiver is available to regularly administer and monitor the treatment.

Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with the use of Exelon/Prometax to the Pharmacovigilance Unit of the Irish Medicines Board (online at www.imb.ie or by Freepost using the yellow card system) or alternatively to the Pharmacovigilance Department at Novartis Ireland Limited (01-2601255.)

Communication information

Should you have any questions or require additional information regarding the use of Exelon/Prometax (rivastigmine), please contact Novartis Ireland Limited at 01-2601255.

Yours sincerely,



Dr. Greg Hays
Medical Director
Novartis Ireland Limited

Enclosure: SPC for Exelon Transdermal Patches (awaiting Commission Decision)