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19th October 2015

Reminyl (galantamine hydrobromide): new warning on the risk of serious skin reactions, Stevens-Johnson syndrome and acute generalised exanthematous pustulosis

Dear Healthcare Professional,

Shire Pharmaceuticals Limited, in agreement with the Health Products Regulatory Authority (HPRA), would like to inform you about important changes to the safety information for galantamine.

Summary

A new warning has been added to the prescribing information for galantamine that describes the following:

- **Serious skin reactions (Stevens Johnson syndrome [SJS] and acute generalised exanthematous pustulosis [AGEP]) have been reported in patients receiving galantamine.**

- **Patients should be informed about the signs of serious skin reactions and that use of galantamine should be discontinued at the first appearance of skin rash.**

In addition, the product information has been modified to include SJS, AGEP and erythema multiforme as new adverse reactions that have been reported rarely with galantamine.

Further information on the safety concern

Following the receipt of a report of a serious skin reaction, Shire Pharmaceuticals Limited conducted a cumulative review of severe cutaneous adverse reactions with galantamine. This led to a subsequent review by the national competent authorities who agreed with the conclusion of Shire Pharmaceuticals Limited., that AEGP, SJS and erythema multiforme are associated with the use of galantamine, although the observed frequency of the reactions is rare.

Further information

Galantamine is indicated for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer type. For further information please refer to the SmPC available on www.hpra.ie

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Call for reporting

As a reminder, there is a need to report any suspected adverse reactions in accordance with the HPRA spontaneous reporting system. When reporting, please provide as much information as possible including information about medical history, any concomitant medication, onset and treatment dates. Suspected adverse reactions should be reported to the HPRA using a Yellow Card obtained either from the HPRA, or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling (01) 676 4971.

Adverse events should also be reported to Shire:
Via e-mail to: GlobalPharmacovigilance@shire.com
Tel. number: +44 1256 894000
Fax number: +44 1256 894715

Company contact point

For questions relating to the content of this communication please contact the Shire Medical Information Department: Tel: 0800 055 6614 Email: medinfoeuceemea@shire.com

Yours faithfully,

Dr Calum Sinclair,
EEA Qualified Person for Pharmacovigilance

Dr Peter Gillberg
Medical Director