

23rd October 2015

REMINYL[®] GALANTAMINE (AS HYDROBROMIDE): NEW WARNING, SERIOUS SKIN REACTIONS (STEVENS-JOHNSON SYNDROME AND ACUTE GENERALIZED EXANTHEMATOUS PUSTULOSIS)

Dear Healthcare Professional,

Janssen Cilag International NV in agreement with the Malta Medicines Authority would like to inform you of the following:

Summary

- A new Warning has been added to the prescribing information for REMINYL[®] (galantamine hydrobromide) that describes the following:
 - Serious skin reactions (Stevens-Johnson syndrome [SJS] and acute generalized exanthematous pustulosis [AGEP]) have been reported in patients receiving REMINYL[®] rarely (may affect up to 1 in 1,000 people).
 - Patients should be informed about the signs of serious skin reactions, and use of REMINYL[®] should be discontinued at the first appearance of skin rash.

In addition, the product information will be modified to include SJS and AGEP as new adverse reactions.

Further information

REMINYL[®] is indicated for the treatment of mild to moderately severe dementia of the Alzheimer type, including Alzheimer's dementia with cerebrovascular disease.

This update to the prescribing information is the result of reviews of the internal safety database containing spontaneous reports of adverse reactions and of the scientific literature, which were undertaken after a case of serious skin reaction was reported. These adverse reactions are reported voluntarily, and it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Call for reporting

Any suspected adverse reactions and medication errors can be reported via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Company contact point

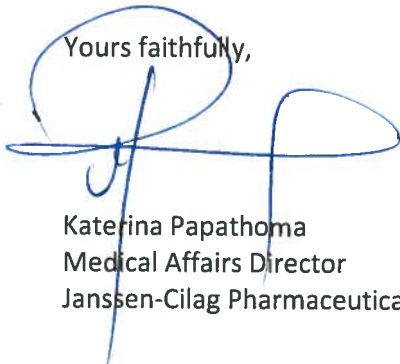
If you have any questions please do not hesitate to contact

Ms. Maria Schmidt, Local PV Contact
Tel: +356 2397 6000
pv@ammangion.com.mt

Or

Mr. Claude Vella Bonanno, RP, Local PV back-up
Tel: +356 2397 6333
rp@ammangion.com.mt

Yours faithfully,



Katerina Papathoma
Medical Affairs Director
Janssen-Cilag Pharmaceutical S.A.C.I.