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Day Month, Year

REMINYL® (galantamine hydrobromide): NEW WARNING AND PRECAUTION, SERIOUS SKIN REACTIONS (STEVENS-JOHNSON SYNDROME AND ACUTE GENERALIZED EXANTHEMATOUS PUSTULOSIS)

Dear Healthcare Professional

Janssen-Cilag Pty Ltd ('Janssen') would like to inform you of important safety information for REMINYL® (galantamine hydrobromide).

New safety information has been added to the WARNINGS AND PRECAUTIONS section of the REMINYL Data Sheet (DS) as follows:

Serious skin reactions (Stevens-Johnson syndrome and acute generalized exanthematous pustulosis) have been reported in patients receiving REMINYL (see Adverse Effects). It is recommended that patients be informed about the signs of serious skin reactions, and that use of REMINYL be discontinued at the first appearance of skin rash.

In addition, the DS has been modified to include Stevens-Johnson syndrome and acute generalized exanthematous pustulosis as new adverse reactions (frequency: very rare (<1/10,000 including isolated reports), see the ADVERSE EFFECTS section, Table 4).

This update to the DS 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.

REMINYL is indicated for the treatment of mild to moderately severe dementia of the Alzheimer type. Please refer to the REMINYL DS, available from Medsafe (at <http://www.medsafe.govt.nz/>) or Janssen's Medical Information Department.

This communication from Janssen is intended to remind you of the importance to share this information with colleagues, patients and caretakers. Janssen is committed to monitoring the safety of our products. We encourage healthcare professionals to report any suspected adverse events for REMINYL to the Centre for Adverse Reactions Monitoring (phone 03 479 7247 or email carmnz@otago.ac.nz) and/or Janssen Medical Information.

If you have further questions, please contact Janssen Medical Information on 0800 800 806 or medinfo@janau.jnj.com

Sincerely

A handwritten signature in blue ink, appearing to read 'L Wall'.

Dr Leanne Wall
Executive Director, Medical and Scientific Affairs
Janssen Australia and New Zealand