

3rd October, 2016

REMINYL® (GALANTAMINE HYDROMROMIDE): New safety information regarding the risk of serious skin reactions associated with the use of REMINYL® (galantamine hydrobromide))

Dear Healthcare Professional,

Janssen-Cilag scientific office in agreement with Saudi food and drug authority would like to inform you of the following:

Summary

- A new Warning will be 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®
 - 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.
- Rare cases of erythema multiforme have been reported in patients receiving REMINYL®

In addition, the product information will be modified to include SJS and AGEP as new adverse reactions. Please refer to the REMINYL® labeling for the specific changes.

Further information

REMINYL® is indicated for the treatment of mild to moderately severe dementia of the Alzheimer type.

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 five cases of serious skin reactions with symptoms of AGEP, SJS or EM were reported.

The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Call for reporting:

Any suspected adverse events should be reported to the national spontaneous reporting system according to the national regulations.

SFDA (National pharmacovigilance and drug safety Center)

Email to: npc.drug@sfd.sa

Fax: +966-11-2057662

Online: <http://ade.sfda.gov.sa/>

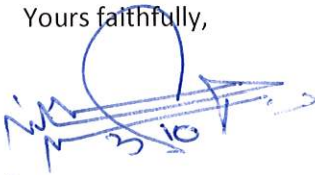
Toll free number: 8002490000

Or you can contact company scientific office at:

Email to: GCC-PV2@its.jnj.com

Fax: +966-11-2153190

Yours faithfully,



Janssen