

Date

Document reference number

*Direct Healthcare Professional Communication on the association of Ebixa®, memantine hydrochloride oral solution with overdose due to administration errors*

Dear Healthcare Professional,

### **Summary**

- **Memantine hydrochloride oral solution delivered by a new pump device was introduced in <include the month-year specific for each Member State, if different from March 2010> . This product replaces memantine oral solution administered by a dropper, which is being phased out. It is estimated that by <specific country date, date provided by the MAH according to the stock in each country, this date will never go beyond February 1st, 2011> droppers will not longer be available in the market.**
- **Several cases of administration error with the new pump device of memantine oral solution, which resulted in overdose. The medication errors resulted from confusion between doses delivered by the new pump device and doses delivered by the dropper.**
- **Healthcare professionals should be aware that there are differences in doses and dose schedules between the pump device and dropper device for memantine.**
- **Dosing for memantine delivered by the pump device is as follows: one actuation of the pump device delivers 0.5mL of solution, corresponding to 5 mg of memantine. The maximum daily dose is 20mg or 4 pump actuations.**
- **Please be vigilant regarding doses and dosing schedules for memantine products, particularly during the transition period from the dropper device to the new pump device. We request that you also advise patients and their caregivers:**
  - **That there is a new pump device for memantine, and give information on how to use the device and the new doses/dosing schedule**
  - **To carefully read the Patient Information Leaflet for memantine oral solution delivered by a pump device**

### **Further information on the safety concern**

In agreement with EMA, H. Lundbeck A/S would like to inform you of cases of administration error with the new pump device of memantine oral solution which, resulted in overdose.

Memantine hydrochloride has been available to treat patients with Alzheimer's disease since 2002 and is administered in the form of tablets or as an oral solution. The new dosing pump device was introduced to the market in <include the month-year specific for each Member State, if different from March 2010> for convenient dosing of the oral solution, and replaces

the dropper device used previously. It is estimated that droppers will not longer be available in the market by <specific country date, date provided by the MAH according to the stock in each country, this date will never go beyond February 1<sup>st</sup>, 2011>.

Up til 9<sup>th</sup> of August 2010, seven (7) cases of administration errors with the dosing pump device have been reported. None of the cases were fatal. One patient was hospitalized for unknown reasons, but recovered; two patients experienced drowsiness and somnolence, which is in accordance with current experience from other memantine overdose cases as described in the Summary of Product Characteristics (SmPC). The remaining five patients did not report any side effects.

The accidental overdoses resulted from confusion between doses of oral memantine administered with a dropper and doses administered with the new pump device. With the new pump device only one pump (0,5ml) delivers 5 mg of memantine.

Patients and their caregivers should therefore be informed that one pump actuation delivers 0.5 mL corresponding to 5 mg memantine hydrochloride and that the maximum dose is 4 pump actuations per day.

Awareness of this potential risk of administration error is particularly important during the transition period from use of a dropper to the pump device. The SmPC and Product Leaflet (PL) for memantine hydrochloride oral solution delivered by a pump device will be updated with clarified wording on this risk, and clear instructions on dose/dose schedules.

Please, refer to the SmPC attached for more detailed information on the pump device (see Annex)

### **Reporting of suspected adverse reactions with the use of Ebixa®**

Any suspected adverse reactions should be reported in accordance with your national reporting system or alternatively to H. Lundbeck by contacting [safety@lundbeck.com](mailto:safety@lundbeck.com).

### **Communication information**

Should you have any questions or require additional information regarding the use of Ebixa®, please contact *medical information on* (national contact)

Jens Peter Balling  
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Annexes (Revised wording for SmPC and PL)