



Wednesday, 11th August 2010

Important Safety Information

Direct Healthcare Professional Communication regarding risk of dosing errors with Xyrem® (sodium oxybate) due to a confusion between gram (g) and millilitre (mL) units

Dear Healthcare Professional,

SUMMARY

- There have been reports of dosing errors with Xyrem® (sodium oxybate) due to a confusion between gram (g) and millilitre (mL) units.
- Please be aware that because the measuring syringe is uniquely graduated in g, the Xyrem® dose must be expressed in g to ensure that patients will administer the correct dose.
- Xyrem® should only be administered with the measuring syringe provided and the syringe should only be used to administer Xyrem®.

FURTHER INFORMATION

Xyrem® (sodium oxybate) is indicated for the treatment of narcolepsy with cataplexy in adult patients.

The recommended starting dose is 4.5 g/day divided into two equal doses of 2.25 g. The dose should be titrated to effect based on efficacy and tolerability up to a maximum of 9 g/day divided into two equal doses of 4.5 g by adjusting up or down in dose increments of 1.5 g/day (i.e. 0.75 g/dose), with a minimum of a one to two weeks period between dose increments.

Since 27th May 2010 the syringe dispensed with Xyrem has a single graduation in g. Before this time, Xyrem was dispensed with a measuring syringe that displayed a double graduation in g and mL.

RECOMMENDATIONS

The dose of Xyrem® must be expressed in g to ensure that patients will administer the correct dose. The syringe provided in the package is uniquely graduated in g and will not measure the correct dose if any other units are used. For example, expressing the dose in mL poses a risk that the patient could administer twice the recommended dose because 2 mL sodium oxybate corresponds to a dose of 1 g.



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Furthermore, Xyrem® should only be administered with the measuring syringe provided and the syringe should only be used to administer Xyrem. If a patient uses the syringe to administer other oral solutions than Xyrem®, dosing errors may occur for these medications since concentrations are likely to be different from that of Xyrem®.

We would appreciate if you could also draw the attention of patients on these important matters. Patients should be advised to check that their dosing instructions are always given in grams.

CALL FOR REPORTING

If you have observed any Xyrem dosing / syringe related incidents or other adverse events, please report this to our medical information on Tel:+44 1753 534655, Fax: +044 1753 536632, E-Mail: medicalinformationuk@ucb.com and /or report directly to the IMB using the online or other reporting options, available on the IMB website:
<http://www.imb.ie/EN/Safety--Quality/Online-Forms/Human-Medicine-Adverse-Drug-Reaction>.

COMMUNICATION INFORMATION

The content of this letter has been endorsed by the European Medicines Agency and has been reviewed by the IMB.

For any further information, please contact UCB (Pharma) Ireland Ltd., United Drug House, Magna Business Park, Citywest Road, Dublin 24, Ireland. Phone: +3531 4637395

Fax: +3531 463 7396

We thank you for your continuous support on this important matter.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Fergal Egan', written over a horizontal line.

Mr. Fergal Egan
General Manager
UCB (Pharma) Ireland Ltd.

A handwritten signature in black ink, appearing to read 'Dr. Asad Khan', written over a horizontal line. The signature is stylized and includes a large loop.

Dr. Asad Khan
Medical Affairs Compliance Manager
UCB Pharma.