

Atypical Antipsychotics



Hyperglycaemia Labelling (February 2003)

EU Hyperglycaemia



EU Hyperglycaemia / Diabetes Class Review for Atypical Antipsychotics is ongoing

Original request: 20 April 2000

Most recent information sent Nov 02 & Feb 03.

Hyperglycaemia



Global labels:

Zyprexa: SPC Warning EU (07/99), US (Other AEs)*, Japan (04/02, CI), Australia (08/02),

Seroquel: SPC Warning Sweden, Denmark (02/03), US (Other AEs), Japan (11/02, CI), NZ (06/02)

Risperdal: SPC Warning UK (12/02) , US (Other events...), Japan (ADR, 09/02)

* Hyperglycemia, hypoglycemia, diabetes mellitus, and diabetic acidosis (all in Adverse Reactions section) - were included in the original USPI dated September 24, 1996. Additional glucose clinical trial data was added to the Adverse Reactions section of the USPI dated April 12, 2000. In addition, diabetic coma was added in this same section and USPI version under Post-introduction Reports. FDA requested removal of glucose clinical trial data text in the version above. Lilly complied in the USPI dated October 27, 2000.



Psychotropic Label Overview for DM

	Zyprexa	Risperdal	Geodon	Clozaril	Seroquel
Black Box					
Contraindication	Jp				Jp
Warning	Jp, EU	UK			Jp, Sw, Dk
Precaution	EU, Au, Jp	UK		US, Au, Ca	Jp
Other (Adverse) Events	US ^a , EU, Au, Jp	US, Jp ^b	US	EU, Au, Ca	US, Jp, NZ
Post Introduction Reports	US ^a , EU	US		US	

^a Hyperglycemia, hypoglycemia, diabetes mellitus, and diabetic acidosis (all in Adverse Reactions section) - were included in the original USPI dated September 24, 1996. Additional glucose clinical trial data was added to the Adverse Reactions section of the USPI dated April 12, 2000. In addition, diabetic coma was added in this same section and USPI version under Post-introduction Reports. FDA requested removal of glucose clinical trial data text in the version above. Lilly complied in the USPI dated October 27, 2000.

^b Hyperglycemia is listed in other adverse reactions under Precautions based on English translation of excerpts from “Notice of Revision of Precautions” issued by Janssen in Sep.2002