
Psychotropic label overview for DM and Lipids

The Lilly logo is written in a black, cursive script font.

Answers That Matter.

Zyprexa label Overview for DM and Lipids

	US	EU	Australia	Japan	Canada
Black Box					
Contraindication				√	
Warning				√	
Precaution		√	√	√	
Adverse Reaction	√	√	√	√	
Post Introduction Reports	√	√			

Source: Analysis from latest PI of Oct 02

Psychotropic Label Overview for DM & Lipids

Time stamp
competitor ?
Maintenance ?

	Zyprexa	Risperdal	Geodon	Clozaril	Seroqual
Black Box					
Contraindication	JP				
Warning	JP				
Precaution	EU, AU, JP	JP		US, AU, CA	US,CA
Adverse Reaction	US, EU, AU, JP	US, AU	US	EU,AU, CA	US,EU, AU,JP
Post Introduction Reports	US, EU	US		US	

high risk

*Context
 why clozine*

US Psychotropic Label for DM & Lipids

	Zyprexa	Risperdal	Geodon	Clozaril	Seroqual
Black Box					
Contraindication					
Warning					
Precaution				√	√
Adverse Reaction	√	√	√		√
Post Introduction Reports	√	√		√	

EU Psychotropic Label for DM & Lipids

	Zyprexa	Risperdal	Geodon*	Clozaril	Seroqual
Black Box					
Contraindication					
Warning					
Precaution	√				√
Adverse Reaction	√			√	√
Post Introduction Reports	√				

*Geodon is not on the market

Risperdal, Geodon, Clozaril and Seroqual are used UK PI as reference

Australia Psychotropic Label for DM & Lipids

	Zyprexa	Risperdal	Geodon	Clozaril	Seroqual
Black Box					
Contraindication					
Warning					
Precaution	√			√	
Adverse Reaction	√	√		√	√
Post Introduction Reports					

Japan Psychotropic Label for DM & Lipids

	Zyprexa	Risperdal	Geodon*	Clozaril*	Seroqual
Black Box					
Contraindication	√				
Warning	√				
Precaution	√	√			
Adverse Reaction	√				√
Post Introduction Reports					

Geodon and Clozaril are not on the market

Canada Psychotropic Label for DM & Lipids

	Zyprexa	Risperdal	Geodon*	Clozaril	Seroqual
Black Box					
Contraindication					
Warning					
Precaution				√	√
Adverse Reaction				√	
Post Introduction Reports					

* Geodon is not on the market

Zyprexa DM & Lipid Label Comparison for Brand Council Affiliates

	US	European Union	Australia	Japan	Canada
Black Box	NA	NA	NA	NA	NA
Contraindication	NA	NA	NA	Patients with diabetes mellitus and those who have a history of diabetes mellitus	NA
Warnings	NA	NA	NA	1. From marked increase in blood glucose, serious adverse reaction such as diabetic ketoacidosis, diabetic coma etc. may appear leading potentially to death. Observe sufficiently with such as measurement of blood glucose during the olanzapine administration 2. Upon administration, explain sufficiently in advance to the patient and family members possible occurrence of above adverse reactions. Provide guidance to them to pay attention to such abnormalities as thirst, polydipsia, polyurea, frequent urination, etc., and to see a physician suspending administration immediately if such symptoms appear.	NA
Precautions	NA	Special warning and special precaution for use: Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been reported very rarely, including some fatal case. In some cases, a prior increase in body weight has been reported which may be a predisposing factor. Appropriate clinical monitoring is advisable in diabetic patients and in patients with risk factors for the development of diabetes mellitus	There is an increased prevalence of diabetes in patients with schizophrenia. As with some other antipsychotics, diabetic coma and diabetic ketoacidosis have been reported in very rare cases, sometimes in patients with no reported history of hyperglycaemia. Appropriate clinical monitoring is advisable in diabetic patients	Careful Administration (in the following patients) Patients with risk factors for diabetes mellitus such as family history of diabetes mellitus, hyperglycemia obesity, etc. Important Precaution 1) By administration of this drug, marked increase in blood glucose may appear leading to fatal clinical course such as diabetic ketoacidosis, diabetic coma, etc. 2) Upon administration, explain sufficiently in advance to the patient and family members possible occurrence of above adverse reactions. Provide guidance to them to pay attention to such abnormalities as thirst, polydipsia, polyurea, frequent urination, etc., and to see a physician suspending administration immediately if such symptoms appear.	NA
Adverse Reactions	Endocrine System-- -Infrequent: diabetes mellitus; Rare: diabetic acidosis. Metabolic and Nutritional Disorders-- -Infrequent: acidosis, hyperglycemia, hypoglycemia; Rare: ketosis.	Undesirable effects: Common(1-10%): Elevated glucose levels. Elevated triglyceride levels.	<u>Adverse events identified from spontaneous post marketing surveillance</u> Metabolic- Very rare (<0.01%): Hyperglycaemia; diabetic coma; diabetic ketoacidosis; exacerbation of pre-existing diabetes; hypertriglyceridemia	Hyperglycemia, Diabetic ketoacidosis, Diabetic coma: Hyperglycemia may develop leading to fatal clinical course, such as diabetic ketoacidosis and diabetic coma leading to death. Thus, make a close observation, with such as blood glucose measurement, (appearance of) thirst, polydipsia, polyurea and frequent urination. If any abnormalities are noted, discontinue administration and take an appropriate measure(s) such as administration of insulin	NA
Post introduction Reports	Diabetic coma	Very rare (<0.01%): Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been spontaneously reported very rarely, including some fatal cases. Hypertriglyceridaemia	NA	NA	NA

US Psychotropic Label Wording for DM & Lipids

	Zyprexa	Risperdal	Geodon	Clozaril	Seroqual
Black Box	NA	NA	NA	NA	NA
Contraindication	NA	NA	NA	NA	NA
Warnings	NA	NA	NA	NA	NA
Precautions	NA	NA	NA	Hyperglycemia: Severe hyperglycemia, sometimes leading to ketoacidosis, has been reported during Clozaril treatment in patients with no prior history of hyperglycemia. While a causal relationship to clozaril use has not been definitively established, glucose levels normalized in most patients after discontinuation of clozaril, and a rechallenge in one patient produced a recurrence of hyperglycemia. The effect of clozaril on glucose metabolism in patients with diabetes mellitus has not been studied. The possibility of impaired glucose tolerance should be considered in patients receiving clozaril who develop symptoms of hyperglycemia, such as polyuria, polyphagia, and weakness. IN patients with significant treatment-emergent hyperglycemia, the discontinuation of clozaril should be considered.	Cholesterol and Triglyceride Elevations: In a pool of 3-6 week placebo-controlled trials, seroquel treated patients had increases from baseline in cholesterol and triglyceride of 11% and 17% respectively, compared to slight decreases for placebo patients. These changes were only weakly related to the increases in weight observed in seroquel treated patients.
Adverse Reactions	Endocrine System-- Infrequent: diabetes mellitus; Rare: diabetic acidosis. Metabolic and Nutritional Disorders-- Infrequent: acidosis, hyperglycemia, hypoglycemia; Rare: ketosis.	Metabolic and Nutritional Disorders: Infrequent: diabetes mellitus. Rare: hypertriglyceridemia, hypoglycemia	Metabolic and Nutritional Disorders: Infrequent: hyperglycemia; Rare: hypoglycemia, glucose tolerance decreased, hypoglycemic reaction, ketosis	NA	Metabolic and Nutritional System: Infrequent: hyperglycemia, hypoglycemia. Endocrine System: Infrequent: diabetes mellitus.
Post introduction Reports	Diabetic coma	Diabetes mellitus aggravated, including diabetic ketoacidosis	NA	Miscellaneous: hyperglycemia	NA

European Union Psychotropic Label Wording for DM & Lipids

	Zyprexa	Risperdal	Geodon*	Clozaril	Seroqual
Black Box	NA	NA		NA	NA
Contraindication	NA	NA		NA	NA
Warnings	NA	NA		NA	NA
Precautions	Special warning and special precaution for use: Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been reported very rarely, including some fatal case. In some cases, a prior increase in body weight has been reported which may be a predisposing factor. Appropriate clinical monitoring is advisable in diabetic patients and in patients with risk factors for the development of diabetes mellitus	NA		NA	NA
Adverse Reactions	Undesirable effects: Common(1-10%): Increased appetite. Elevated glucose levels. Elevated triglyceride levels.	NA		Severe hyperglycaemia, sometimes leading to ketoacidosis, has been reported during CLOZARIL (clozapine) treatment in patients with no prior history of hyperglycaemia. Blood glucose levels normalised in most patients after discontinuation of CLOZARIL (clozapine), and a rechallenge in a few cases produced a recurrence of hyperglycaemia. The possibility of impaired glucose tolerance should be considered in patients receiving CLOZARIL (clozapine) particularly if symptoms of polydipsia, polyuria, and weakness develop. In patients with significant treatment-emergent hyperglycaemia, the discontinuation of CLOZARIL (clozapine) should be considered when active medical management of the hyperglycaemia has failed.	Small elevations in non-fasting serum triglyceride levels and total cholesterol have been observed during treatment with SEROQUEL.
Post introduction Reports	Very rare (<0.01%): Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been spontaneously reported very rarely, including some fatal cases. Hypertriglyceridaemia	NA		NA	NA

*Geodon is not on the market

Risperdal, Geodon, Clozaril and Seroqual are used UK PI as reference

Australia Psychotropic Label Wording for DM & Lipids

	Zyprexa	Risperdal	Geodon	Clozaril	Seroqual
Black Box	NA	NA	NA	NA	NA
Contraindication	NA	NA	NA	NA	NA
Warnings	NA	NA	NA	NA	NA
Precautions	There is an increased prevalence of diabetes in patients with schizophrenia. As with some other antipsychotics, diabetic coma and diabetic ketoacidosis have been reported in very rare cases, sometimes in patients with no reported history of hyperglycaemia. Appropriate clinical monitoring is advisable in diabetic patients	NA	NA	On rare occasions, severe hyperglycaemia, sometimes leading to ketoacidosis/hypersomolar coma, has been reported during Clozaril treatment in patients with no prior history of hyperglycaemia. While a causal relationship to Clozaril use has not been definitely established, glucose levels returned to normal in most patients after discontinuation of Clozaril, and rechallenge produced a recurrence of hyperglycaemia in a few cases. The effect of Clozaril on glucose metabolism in patients with diabetes mellitus has not been studied. The possibility of impaired glucose tolerance should be considered in patients receiving Clozaril who develop symptoms of hyperglycaemia, such as polydipsia, polyuria, polyphagia or weakness. In patients with significant treatment-emergent hyperglycaemia, discontinuation of Clozaril should be considered.	NA
Adverse Reactions	<u>Adverse events identified from spontaneous post marketing surveillance</u> Metabolic- Very rare (<0.01%): Hyperglycaemia;diabetic coma;diabetic ketoacidosis;exacerbation of pre-existing diabetes;hypertriglyceridemia	Hyperglycaemia and exacerbations of pre-existing diabetes have been reported in very rare cases during risperidone treatment	NA	Severe hyperglycaemia, sometimes leading to ketoacidosis/hyperosmolar coma, has been reported rarely during Clozaril treatment in patients with no prior history of hyperglycaemia	Hyperlipemia observed as adverse events was also recorded during clinical trial with a frequency less than 1%
Post introduction Reports		NA	NA	NA	NA

Japan Psychotropic Label Wording for DM & Lipids

	Zyprexa	Risperdal**	Geodon*	Clozaril*	Seroqual **
Black Box	NA				
Contraindicati on	Patients with diabetes mellitus and those who have a history of diabetes mellitus				
Warnings	1.From marked increase in blood glucose, serious adverse reaction such as diabetic ketoacidosis, diabetic coma etc.may appear leading potentially to death.Observe sufficiently with such as measurement of blood glucose during the olanzapine administration 2.Upon administration, explain sufficiently in advance to the patient and family members possible occurrence of above adverse reactions. Provide guidance to them to pay attention to such abnormalities as thirst, polydipsia, polyurea, frequent urination, etc.,and to see a physician suspending administration immediately if such symptoms appear.				
Precautions	Careful Administration (in the following patients) Patients with risk factors for diabetes mellitus such as family history of diabetes mellitus, hyperglycemia obesity,etc. Important Precaution 1)By administration of this drug, marked increase in blood glucose may appear leading to fatal clinical course such as diabetic ketoacidosis, diabetic coma, etc. Observe sufficiently with such as measurement of blood glucose,(appearance of thirst, polydipsia, polyurea, and frequent urination during the olanzapine administration. In particular, patients with risk factors for diabetes mellitus such as hyperglycemia,obesity,etc.,blood glucose may increase, leading to acute worsening of metabolic state. 2) Upon administration, explain sufficiently in advance to the patient and family members possible occurrence of above adverse reactions. Provide guidance to them to pay attention to such abnormalities as thirst, polydipsia, polyurea, frequent urination, etc.,and to see a physician suspending administration immediately if such symptoms appear.	“Hyperglycemia”has been added on the section of “Other adverse reaction” under Precautions by Janssen			
Adverse Reactions	Hyperglycemia, Diabetic ketoacidosis, Diabetic coma:Hyperglycemia may develop leading to fatal clinical course, such as diabetic ketoacidosis and diabetic coma leading to death. Thus, make a close observation, with such as blood glucose measurement,(appearance of) thirst,polydipsia,polyurea and frequent urination.If any abnormalities are noted,discontinue administration and take an appropriate measure(s)such as administration of insulin				“Hyperglycemia”has been added on the section of “Other adverse reactions” by AstraZeneca
Post introduction Reports	NA				

*Geodon and Clozaril are not on the market

**the language was translated by ELJKK from Japanese to English that were released by Janssen and AZ for the proactive label changes for their respective products.