For Effective glycemic control

Piriglim®

Glimepiride

CODAL-SYNTO

PIRIGLIM® 1mg tablets • **PIRIGLIM®** 2mg tablets
PIRIGLIM® 3mg tablets • **PIRIGLIM®** 4mg tablets

Summary of SPC for Piriglim®

Trade Name of the Medicinal Product:	Piriglim®
Qualitative and Quantitative Composition:	Glimepiride 1mg, 2mg, 3mg or 4mg.
Therapeutic indications:	The treatment of type 2 diabetes mellitus, when diet, physical exercise and weight reduction alone are not adequate.
Posology and Method of Administration:	The starting dose is 1 mg glimepiride per day. If good control is achieved this dosage should be used for maintenance therapy. If control is unsatisfactory the dosage should be increased, based on the glycaemic control, in a stepwise manner with an interval of about 1 to 2 weeks between each step, to 2, 3 or 4 mg glimepiride per day. The maximum recommended dose is 6 mg glimepiride per day.
Contra-indications:	Hypersensitivity, insulin dependent diabetes, diabetic coma, ketoacidosis, severe renal or hepatic function disorders.
Special Warnings and Precautions for Use:	Piriglim must be taken shortly before or during a meal. When meals are taken at irregular hours or skipped altogether, treatment with Piriglim may lead to hypoglycaemia. Factors favouring hypoglycaemia include: unwillingness or incapacity of the patient to cooperate, undernutrition, irregular mealtimes or missed meals or periods of fasting, alterations in diet, imbalance between physical exertion and carbohydrate intake, consumption of alcohol, impaired renal function, serious liver dysfunction, overdosage, certain uncompensated disorders of the endocrine system, and concurrent administration of certain other medicines. Treatment with Fertin requires regular monitoring of glucose levels in blood and urine, determination of the proportion of glycosylated haemoglobin, hepatic and haematological monitoring. In stress-situations a temporary switch to insulin may be indicated. In patients with severe impairment of renal or liver function change over to insulin is indicated. Treatment of patients with G6PD-deficiency with sulfonylurea agents can lead to hemolytic anaemia. Piriglim contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorbtion should not take this medicine.
Interactions with other Medicaments and other forms of Interaction:	Glimepiride is metabolised by cytochrome P450 2C9 (CYP2C9). Its metabolism is known to be influenced by concomitant administration of CYP2C9 inducers (e.g. rifampicin) or inhibitors (e.g. fluconazole).
Pregnancy and Lactation:	In case of treatment by glimepiride, if the patient plans to become pregnant or if a pregnancy is discovered, the treatment should be switched as soon as possible to insulin therapy. Lactation: Breast-feeding is advised against during treatment with glimepiride.
Undesirable Effects:	Leukocytoclastic vasculitis, mild hypersensitivity reactions that may develop into serious reactions and sometimes shock, cross-allergenicity with sulphonylureas, sulphonamides or related substances, thrombocytopenia, leucopenia, granulocytopenia, agranulocytosis, erythrocytopenia, haemolytic anaemia, pancytopenia, hypoglycaemic reactions, transient visual disturbances, nausea, vomiting, diarrhoea, abdominal distension, abdominal discomfort, abdominal pain, elevation of liver enzymes, impairment of liver function, hepatitis and liver failure, hypersensitivity reactions of the skin, and decrease in blood sodium.
	MAH: Codal Synto Ltd.