VI.2 Elements for a Public Summary

[Product Name] 60 mg modified-release tablets

VI.2.1 Overview of disease epidemiology

Diabetes mellitus is a metabolic disease characterised by increased levels of blood sugar. If the human body is incapable of producing insulin properly, the patient is suffering from Type 1 diabetes mellitus (T1DM), also known as insulin-dependent diabetes mellitus. These patients have to inject insulin. If, in contrast, the body acquires insulin resistance, meaning, the body cells lose their ability to absorb and process insulin correctly, the patient is suffering from Type 2 diabetes mellitus (T2DM).

The prevalence in economically developed countries is estimated to be 15-20%.Obesity is thought to be the main cause of T2DM, and the risk of T2DM increases with age. Due to the demographic change, the globally proceeding industrialisation, urbanisation and the simultaneously decreasing physical activity of humans, the prevalence of T2DM is increasing worldwide.

Countries with a high prevalence of T2DM are Saudi Arabia, the USA and Switzerland, whereas countries with low prevalence are China and Iceland. It is assumed that in 2030, the number of patients with T2DM will have doubled in China. While the number of diabetic patients was about 171 million worldwide in 2000, forecasts for 2030 assume that 366 million patients will be affected.

VI.2.2 Summary of treatment benefits

[Product Name] modified-release tablets is a medicine that contains the active ingredient gliclazide that reduces blood sugar levels (oral antidiabetic medicine belonging to the sulphonylurea group).

[Product Name] 60 mg is used in a certain form of diabetes (type 2 diabetes mellitus) in adults, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

VI.2.3 Unknowns relating to treatment benefits

The safety and efficacy of gliclazide in children and adolescents have not been established. No data are available in children.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Low blood sugar (Hypoglycaemia)	Gliclazide should only be taken if you have regular food intake otherwise you may develop a low blood sugar up to coma. You can experience too low blood sugar when you e.g. – take too much exercise without eating an adequate amount of carbohydrates – skip meals or have irregular meals – have kidney or liver insufficiency – accidentally overdose on gliclazide tablets	During Gliclazide treatment regular monitoring of your blood (and possibly urine) sugar levels and also your glycated haemoglobin (hbA1c) is necessary. In the first few weeks of treatment the risk of having reducing blood sugar levels (hypoglycaemia) may be increased. So close monitoring is necessary. Be aware of symptoms of a low blood sugar level (hypoglycaemia) including sweating, shaking, paleness, hunger, headache, irregular or fast heart beat, blurred vision, irritability, forgetfulness and confusion. To prevent coma, in most cases of low blood sugar levels, symptoms will resolve if you consume sugar in a drink or food.
Severe skin reactions with blistering (Serious skin reactions, including bullous reactions (such as Stevens-Johnson syndrome and toxic epidermal necrolysis)	Bullous skin reactions (extensive changes of the skin or mucous membranes with redness, scaling, and large blisters), including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been observed.	If you notice blistering of your skin, mouth or genitals, **immediately** stop using gliclazide.

Insulin-dependent diabetes (Use in patients with type 1 diabetes)	[Product Name] 60 mg modified-release tablets is used to keep blood sugar at the correct level in adults with diabetes when it is not controlled by dietary measures, physical exercise and weight loss alone. Gliclazide is not effective in insulin-dependent diabetes.	Do not take [Product Name] 60 mg modified-release tablets if you have insulin-dependent (Type 1) diabetes
Severe kidney or liver disease (Use in patients with severe renal or hepatic insufficiency)	Gliclazide is mainly metabolised in the liver and excreted in the urine. Severe kidney or liver disease can result in an increased risk of developing adverse drug reactions.	Do not take [Product Name] 60 mg modified-release tablets if you have severe kidney or liver disease
Increase in blood glucose levels following concomitant use of danazol, chlorpromazine, glucocorticoids, ritodrine, salbutamol, terbutaline (i.v.)	The blood glucose lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the mentioned medicines is taken.	Consult your doctor before you start taking another medicine. If you go into hospital tell the medical staff you are taking [Product Name] 60 mg modified-release tablets.
Poor blood glucose control	The blood glucose lowering efficacy of any oral antidiabetic agent, including gliclazide, can decrease over time. This can be caused by the increase of the severity of the diabetes or by the reduction of the response to the drug. Therefore dose adjustment, dietary compliance or a change in medication must be considered.	Blood glucose control during the antidiabetic treatment may be affected by any of the following: fever, trauma, infection or surgical intervention. Consult your doctor, when your blood glucose levels differ significantly.
Liver disorders (including hepatitis, cholestatic jaundice)	gliclazide-containing products can cause • liver problems including hepatitis • yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)	There have been isolated reports of abnormal liver function, which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Concomitant use of gliclazide with anticoagulant therapy	[Product Name] may increase the effects of medicines which reduce blood clotting (e.g. warfarin).
Haemolytic anaemia	Lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur in patients missing the enzyme glucose-6-phosphate dehydrogenase. If you know you have a family history of glucose-6-phosphate dehydrogenase deficiency or if you know you suffer from this condition, you should talk to your doctor before taking [Product Name] 60 mg modified-release tablets.

Important missing information

Risk	What is known
Use in pregnancy and lactation	There is no experience with the use of gliclazide during pregnancy in humans, even though there are few data with other sulphonylureas. Gliclazide is not recommended for use during pregnancy.
Use in paediatric population	The safety and efficacy of [Product Name] 60 mg modified-release tablets in children and adolescents have not been established.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable.