EMA/760390/2014

Summary of the risk management plan (RMP) for Abasaglar[1] (insulin glargine)

This is a summary of the risk management plan (RMP) for Abasaglar, which details the measures to be taken in order to ensure that Abasaglar is used as safely as possible. For more information on RMP summaries, see here.

This RMP summary should be read in conjunction with the EPAR summary and the product information for Abasaglar, which can be found on Abasaglar's EPAR page.

Overview of disease epidemiology

Abasaglar is a medicine used to treat diabetes in adults and children over the age of two. Diabetes is a condition in which the pancreas does not make enough insulin to control the level of glucose (sugar) in the blood or when the body is unable to use insulin effectively.

There are two types of diabetes, type 1 and type 2:

- Type 1 is less common (5%-10% of patients). In 2010, about 112,000 children under 14 years of age in Europe were estimated to have this condition. It is usually diagnosed early in life and commonly runs in families.
- Type 2 is more common (90%-95% of patients). In 2010, about 1 out of every 15 adults in Europe had this condition. Type 2 diabetes is more likely to develop in people who have family members with the condition, people with an ethnic background known to be associated with a higher risk (for example Asian or African), people aged over 40 years old or who are overweight or obese, do not exercise, have high blood pressure or smoke.

People with diabetes are at greater risk of developing conditions such as cardiovascular disorders, neurological (nervous system) disorders, diabetic eye disease and kidney disease.

Summary of treatment benefits

Abasaglar contains the active substance insulin glargine. It is a biosimilar medicine, which means it is similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Abasaglar is Lantus, which also contains insulin glargine, and studies were designed to compare Abasaglar with Lantus.

Studies were carried out to show that the way Abasaglar is absorbed into the body and the way it acts on blood glucose were similar to Lantus. In addition, treatment with once-daily Abasaglar has been shown to be comparable to the reference medicine, Lantus, in two supportive studies involving a total of 1,295 adults with diabetes. In one study in 536 patients with type 1 diabetes, Abasaglar was compared with Lantus when added to short-acting insulin treatment. In the second study in 759 patients with type 2 diabetes, treatment with Abasaglar was compared with Lantus as an addition to

[1] Previously known as Abasria.

diabetes medicines taken by mouth. Both studies showed that Abasaglar was of benefit in controlling blood glucose and was comparable in its effect to Lantus.

Unknowns relating to treatment benefits

Because the studies with Abasaglar were designed to establish its similarity to Lantus, any uncertainties regarding its benefits are considered to be the same as for the reference medicine.. There are no studies of the use of Abasaglar in pregnancy and in children below 2 years of age.

Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Low blood sugar	Low blood sugar is the most common side effect of treating diabetes with insulin and is seen in more than 1 patient in 10 treated with insulin glargine. It is associated with feeling sick (nauseous), confused, lightheaded, dizzy, and jittery. If the patient does not eat some carbohydrate, more serious symptoms, like passing out or, rarely, having a seizure, can occur.	Blood glucose levels should be monitored regularly, and the timing and dose of insulin should be adjusted to take account of the blood-glucose reading, as well as mealtimes and exercise regimens.
Allergic reaction to the medicine	Immediate allergic reactions to insulin (including insulin glargine) are rare, affecting up to 1 patient in 1000, but may include skin reactions such as itching and rash, swelling of tissue around the neck, face, mouth and/or throat, difficulty breathing, low blood pressure and shock, all of which may become life-threatening.	The product information for Abasaglar contains warnings for doctors and patients on the possible risks of allergic reactions. Patients must not use this medicine if they are allergic to it or to any of its ingredients.
Reactions at the injection site	Reactions at the injection site, such as redness, swelling, soreness, and itching are common (seen in up to 1 patient in 10).	The product information for Abasaglar contains warnings for doctors and patients on the likelihood of injection site reactions.
Taking the wrong kind of insulin (medication error)	It is possible that patients who need to inject both a long-acting insulin and regular mealtime insulin may inject the wrong insulin. There are also reports of patients not knowing the exact brand (type) of insulin they are supposed to be taking.	The insulin label must always be checked before each injection to ensure the right insulin is injected.

Important potential risks

Risk	What is known
Cancer (malignancies)	Some data have suggested that there may be a small increased risk of cancer with insulin glargine treatment. However, results from a recent large long-term study in patients with pre-diabetes or diabetes called the ORIGIN trial showed that there was no difference in cancer risk when therapy with insulin glargine was compared with usual care.
Antibody development (immunogenicity)	Taking insulin (including insulin glargine) may cause the immune system (the body's natural defences) to produce antibodies targeted against insulin. In rare cases, these antibodies can neutralise the effects of insulin so that the doctor has to change the type of insulin or the insulin dose.

Missing information

Risk	What is known
Use in pregnancy	Abasaglar has not been studied in pregnant or breastfeeding women. However, results in some women who have used insulin glargine during pregnancy have not linked its use to any specific harmful effects on pregnancy or the developing baby. As careful control of blood sugar during pregnancy is important, use of Abasaglar may be considered. The medicine would not be expected to affect breastfed infants.
Use in children less than 2 years of age	Insulin glargine has not been studied in children less than 2 years old.

Summary of risk minimisation measures by safety concern

All medicines have a summary of product characteristics (SmPC) which provides physicians, pharmacists and other healthcare professionals with details on how to use the medicine, and also describes the risks and recommendations for minimising them. Information for patients is available in lay language in the package leaflet. The measures listed in these documents are known as 'routine risk minimisation measures'.

The SmPC and the package leaflet are part of the medicine's product information. The product information for Abasaglar can be found on Abasaglar's EPAR page.

This medicine has no additional risk minimisation measures.

Planned post-authorisation development plan

Not applicable.

Summary of changes to the risk management plan over time

Not applicable.

This summary was last updated in 01-2015.