Presentation

Abasaglar is a clear, colourless, sterile solution of 100 units/ml (equivalent to 3.64mg) insulin glargine (rDNA origin), available as either 3ml cartridge or 3ml KwikPen. Each cartridge/pen contains 300 units of insulin glargine in 3ml solution.

Uses

Treatment of diabetes mellitus in adults, adolescents, and children aged 2 years and above.

Dosage and Administration

The dose regimen (dose and timing) should be individually adjusted. In patients with Type 2 diabetes mellitus, Abasaglar can also be given together with orally active antidiabetic medication.

Abasaglar has a prolonged duration of action, and should be administered once daily at any time, but at the same time each day. It should only be given by subcutaneous injection and should not be administered intravenously. Injection sites must be rotated within a given injection area from one injection to the next.

Abasaglar must not be mixed with any other insulin or diluted.

When changing from another intermediate or long-acting insulin treatment regimen to Abasaglar, a change of the dose of the basal insulin may be required and the concomitant antidiabetic treatment may need to be adjusted (dose and timing of additional regular insulins or fast-acting insulin analogues, or the dose of oral antidiabetic medicinal products).

Contra-indications

Hypersensitivity to insulin glargine or any of the excipients.

Warnings and Special Precautions

Abasaglar is not the insulin of choice for the treatment of diabetic ketoacidosis.

In case of insufficient glucose control, or tendency to hyper- or hypoglycaemic episodes, other relevant factors must be reviewed before dose adjustment is considered.

Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand, type, origin, and/or method of manufacture may result in the need for a change in dose.

In rare cases, insulin antibodies may necessitate dose adjustment.

The time of occurrence of hypoglycaemia may change when the insulin regimen is changed, depending on the action profile of the insulins used.

Caution and intensified glucose monitoring are advised in patients for whom hypoglycaemia might be of particular clinical relevance.
Patients should be aware that warning symptoms of hypoglycaemia may be changed, less pronounced, or absent in certain circumstances, including: markedly improved glycaemic control; when hypoglycaemia develops gradually; in the elderly; after transfer from animal to human insulin; autonomic neuropathy; long history of diabetes; psychiatric illness; use of certain medications such as beta-blockers. This may result in severe hypoglycaemia.

The prolonged effect of insulin glargine may delay recovery from hypoglycaemia.

If HbA1c is low, consider possibility of recurrent, unrecognised hypoglycaemia.

Adherence of the patient to the dose and dietary regimen, correct insulin administration, and awareness of hypoglycaemia symptoms are essential to reduce risk of hypoglycaemia. Factors increasing risk of hypoglycaemia require particularly close monitoring and may necessitate dose adjustment.

Intercurrent illness requires intensified monitoring. Testing for ketones and dose adjustment may be necessary. Patients with Type 1 diabetes must continue to consume at least small amounts of carbohydrate and must never omit insulin entirely.

The cartridges should only be used in a pen recommended for the use with Lilly insulin cartridges.

The insulin label must always be checked before each injection to avoid medication errors.

Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin. If the combination is used, patients should be observed for signs and symptoms of heart failure and pioglitazone discontinued if any deterioration occurs.

**Pregnancy and Lactation**

No clinical data from controlled studies are available. Data from >1,000 pregnancy outcomes indicate no specific adverse effects of insulin glargine on pregnancy and no specific malformative nor feto/neonatal toxicity. The use of Abasaglar may be considered during pregnancy, if necessary.

Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters. Immediately after delivery, insulin requirements decline rapidly. Careful monitoring of glucose control is essential.

**Driving, etc**

The patient’s ability to concentrate and react may be impaired as a result of hypo- or hyperglycaemia, or visual impairment. This may constitute a risk in situations where these abilities are of special importance (e.g., driving a car or operating machines).

**Undesirable Effects**

Hypoglycaemia is very common. Injection site reactions and lipohypertrophy are common. Immediate-type allergic reactions are rare, but may be life-threatening.

*For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at http://www.medicines.ie/.*

**Legal Category** POM
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