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Amglidia *(glibenclamide)*

An overview of Amglidia and why it is authorised in the EU

What is Amglidia and what is it used for?

Amglidia is a medicine used to treat newborns and children with neonatal diabetes, a form of diabetes that occurs in the first 6 months of life and that requires treatment with insulin. Amglidia was shown to be effective in patients with whose disease was caused by certain genetic mutations.

Amglidia contains the active substance glibenclamide.

Neonatal diabetes is rare, and Amglidia was designated an 'orphan medicine' (a medicine used in rare diseases) on 15 January 2016. Further information on the orphan designation can be found here: ema.europa.eu/Find medicine/Human medicines/Rare disease designation

Amglidia is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but is available in a different formulation. While the reference medicine Daonil is given as tablets, Amglidia is available as a liquid (suspension).

How is Amglidia used?

Amglidia should be started by a specialist experienced in the treatment of patients with very early onset diabetes and can only be obtained with a prescription. The medicine is available as a liquid to be taken by mouth using a syringe. It can be used with insulin and the recommended dose depends on the child's bodyweight and blood glucose levels, and is split into two daily administrations. The dose is increased over the first 4 weeks until blood glucose levels are under control and as the dose is increased, it is usually possible to reduce and even stop the regular insulin.

For more information about using Amglidia, see the package leaflet or contact your doctor or pharmacist.

How does Amglidia work?

In many newborn babies with neonatal diabetes, the cells in the pancreas produce insulin but they are not able to release it into the blood to control the level of blood glucose. The lack of insulin in the blood causes symptoms of diabetes.

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The active substance in Amglidia, glibenclamide, is a diabetes medicine that belongs to the class of sulfonylureas. It works on insulin-producing cells in the pancreas and attaches to channels on their surface called KATP channels, involved in triggering the release of insulin. By attaching to these channels, glibenclamide restores the cells`ability to release insulin into the blood, reducing the symptoms of diabetes.

What benefits of Amglidia have been shown in studies?

The company provided data from the published literature on glibenclamide given as crushed tablets. These data show that in patients who were switched from insulin to glibenclamide, blood glucose remained controlled over time (measured as glycosylated haemoglobin (HbA_{1c})).

A study evaluated 10 children with neonatal diabetes who were treated with glibenclamide given as crushed tablets and who were switched to the oral suspension. Blood glucose remained under control whether patients were taking crushed tablets or oral suspension.

In addition, a study involving 18 healthy adults showed that glibenclamide given as a suspension produced a similar level of glibenclamide in the body as glibenclamide given as crushed tablets.

What are the risks associated with Amglidia?

The most common side effects with Amglidia (which may affect more than 1 in 10 people) are hypoglycaemia (low blood glucose levels), diarrhoea and abdominal pain (stomach ache). The most serious side effect is hypoglycaemia. For the full list of side effects of Amglidia, see the package leaflet.

Amglidia must not be used in people who are hypersensitive (allergic) to glibenclamide, other sulphonylureas or any of the other ingredients. It must not be used in patients who have complications of diabetes (diabetic ketoacidosis), take the medicine bosentan, have porphyria (an inability to break down chemicals called porphyrins) or have severe problems with their liver or kidneys. For the full list of restrictions, see the package leaflet.

Why is Amglidia authorised in the EU?

Glibenclamide has been used to treat neonatal diabetes for many years, however it was not licensed for this use and an age-appropriate formulation was not available. Although limited, available data show that sulfonylureas such as glibenclamide have beneficial effects on blood glucose levels in patients with neonatal diabetes and allow their regular insulin use to be reduced or stopped. In terms of side effects, these are widely known and considered manageable. The European Medicines Agency therefore decided that Amglidia's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Amglidia?

The company that markets Amglidia will issue educational materials for healthcare professionals with detailed information on the different presentations available and how to avoid mix-ups between them.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Amglidia have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Amglidia are continuously monitored. Side effects reported with Amglidia are carefully evaluated and any necessary action taken to protect patients.

Other information about Amglidia

Amglidia received a marketing authorisation valid throughout the EU on 24.05.2018.

Further information on Amglidia can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 05-2018.