22 February 2018
EMA/102426/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Amglidia

glibenclamide

On 22 February 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Amglidia, intended for the treatment of neonatal diabetes. Amglidia was designated as an orphan medicinal product on 15 January 2016. The applicant for this medicinal product is Ammtek.

Amglidia will be available as an oral suspension (0.6 mg/ml and 6 mg/ml). The active substance of Amglidia is glibenclamide, a sulfonylurea (ATC code: A10BB01) which stimulates insulin release from pancreatic beta-cells by inhibiting ATP-sensitive potassium channels.

The benefits with Amglidia are its ability to improve glycaemic control. The most common side effects are hypoglycaemia, transitory diarrhoea and abdominal pain.

Amglidia is a hybrid medicine[2] of Daonil which has been authorised in the EU since 1 January 1969. Amglidia contains the same active substance as Daonil, but is approved for a different indication, and is available in a different formulation and strength. Studies have demonstrated the satisfactory quality, and relative bio-availability of Amglidia.

The full indication is:

> "AMGLIDIA is indicated for the treatment of neonatal diabetes mellitus, for use in newborns, infants and children.
>
> Sulphonylureas like AMGLIDIA have been shown to be effective in patients with mutations in the genes coding for the β-cell ATP-sensitive potassium channel and chromosome 6q24-related transient neonatal diabetes mellitus."

It is proposed that Amglidia be started by a physician experienced in the treatment of patients with very early onset diabetes.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.