



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 August 2018
EMA/133231/2018

Guide to be given to prescribers to ensure Amglidia is used correctly

Guide will increase awareness on the different medicine presentations and help avoid medication errors

All healthcare professionals who are expected to prescribe Amglidia (glibenclamide oral suspension) will be provided with a guide to help ensure that the medicine is prescribed and used correctly.

Amglidia is a medicine used for the treatment of neonatal diabetes, a form of diabetes that occurs in the first 6 months of life.

Amglidia is available as an oral suspension in two strengths: 0.6 mg/ml and 6 mg/ml, and each strength is available in two presentations: either with a 1-ml oral syringe or with a 5-ml oral syringe. The strength and the size of the oral syringe to be used depends on the dose prescribed. It is important that only the syringe provided with the pack is used to measure Amglidia.

Dosing errors may occur due to confusion between milligram (mg) and millilitre (ml), or use of incorrect strength or size of syringe and how the dose is measured, which may result in too high or too low blood sugar levels.

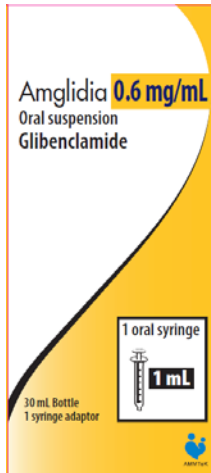
To avoid medication errors, prescribers will be given a guide specifying which strength and presentation to use and what details to include on each prescription.

Information for parents and carers

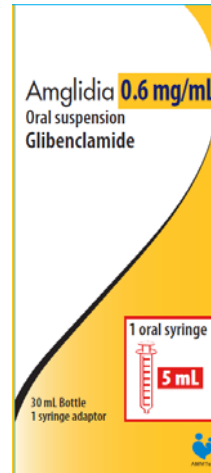
- Amglidia is used to treat neonatal diabetes, a form of diabetes that occurs in the first 6 months of life. It is a liquid to be given by mouth and is available in two strengths: 0.6 mg/ml and 6 mg/ml. Each strength is available in two presentations: either with a 1-ml oral syringe or with a 5-ml oral syringe (see picture below).
- Amglidia is given twice a day. The dose is prescribed in millilitre (ml) according to body weight. When prescribing the medicine, the doctor will also specify the strength of Amglidia and the correct size of the oral syringe to give this dose accurately.



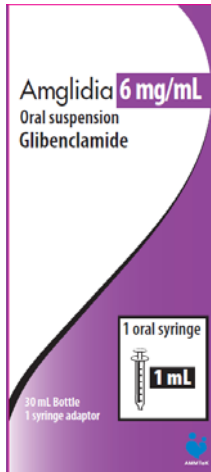
Amglidia 0.6 mg/ml, with 1 ml syringe



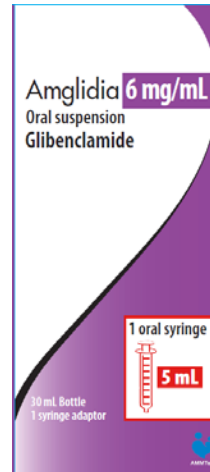
Amglidia 0.6 mg/ml, with 5 ml syringe



Amglidia 6 mg/ml, with 1 ml syringe



Amglidia 6 mg/ml, with 5 ml syringe



- Parents and carers will be advised by their healthcare professional on how to draw up the medicine into the oral syringe and give a dose to the child.
- Parents and carers should use only the oral syringe provided with the package to measure the dose of Amglidia.
- Parents and carers should always use Amglidia as advised by the doctor. Parents and carers should speak to a doctor or pharmacist if they have any questions about the treatment.

Information for healthcare professionals

- Amglidia is an oral suspension available in two strengths: 0.6 mg/ml and 6 mg/ml. There are two presentations for each strength: one with an oral syringe of 1 ml and one with an oral syringe of 5 ml (see picture above).
- Amglidia 0.6 mg/ml strength should only be used for doses up to 0.6 mg/kg daily. This is to limit the exposure to the sodium benzoate excipient. Amglidia 6 mg/ml should be used for doses higher than 0.6 mg/kg daily.

- The choice of the oral syringe depends on the volume per dose:
 - If the volume per dose is equal to or less than 1 ml, the 1-ml oral syringe should be prescribed;
 - If the volume per dose is more than 1 ml, the 5-ml oral syringe should be prescribed.
- Only the oral syringe provided with the package should be used to measure the dose of Amglidia.
- The prescription should include all of the following details:
 - strength of Amglidia,
 - daily dose of Amglidia in ml,
 - volume in ml to be given for each dose,
 - how many doses are given each day,
 - size of the oral syringe to be used.
- Healthcare professionals should explain to the parent or carer that the dose of Amglidia is prescribed in ml according to the patient's body weight. Healthcare professionals should also explain that the dose is to be given with the oral syringe graduated in ml, provided in the pack.
- Pharmacists should ensure that the correct strength of Amglidia and the correct size of oral syringe are dispensed.
- If the patient is switched to a different strength or a different oral syringe is appropriate, the prescriber should highlight to the parent or carer the packaging differences and carefully explain how to measure the new dose.

More about the medicine

Amglidia is a diabetes medicine used for neonatal diabetes, a form of diabetes that occurs in the first 6 months of life and that requires treatment with insulin. Once Amglidia is started, it is usually possible to reduce and even stop the dose of insulin the patient is already receiving. Amglidia is effective in patients with specific genetic mutations (beta-cell ATP-sensitive potassium channel and chromosome 6q24).

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 special channels on their surface called ATP-sensitive potassium channels (KATP channels), through which potassium ions normally enter the cells and trigger the release of insulin. Glibenclamide's effect on the KATP channel restores the cells' ability to release insulin into the blood.

More information on Amglidia can be found on the Agency's website: ema.europa.eu/Find_medicine.