swissmedic

Public Summary SwissPAR dated 9 March 2021

Carbaglu® (active substance: carglumic acid)

First authorisation in Switzerland: 28 July 2020

Medicine for the treatment of high blood levels of ammonia (hyperammonaemia)

About the medicinal product

The medicinal product Carbaglu, containing the active substance carglumic acid, is available as a dispersible tablet. This can be divided and dissolved in at least 5-10 ml of water and taken either by mouth or via a nasogastric tube. Carbaglu can be used on its own.

Carbaglu can help eliminate high blood levels of ammonia (hyperammonaemia). Ammonia is especially toxic for the brain and leads, in severe cases, to reduced levels of consciousness and to coma.

Hyperammonaemia may be due to

- the lack of a specific liver enzyme, N-acetylglutamate synthase. Patients suffering from this rare disorder are not able to eliminate nitrogen waste products, which build up after eating protein. Since this disorder persists during the entire life of the affected patient, the need for this treatment is lifelong.
- Isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia (functional disorders of certain enzymes involved in specific steps of amino acid metabolism).

Patients suffering from one of these disorders need treatment during the hyperammonaemia crisis.

The medicine has been authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements. Medicinal products of this kind benefit from simplified authorisation conditions in Switzerland.

Information on authorisation

In deciding whether to authorise the medicinal product Carbaglu with the active substance carglumic acid, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA).

The assessment of the clinical data was based on the assessment reports issued by the EMA and the FDA and the corresponding product information texts.

Swissmedic authorised Carbaglu in Switzerland on 28 July 2020.

Since the assessment of the clinical data was based on the assessment reports of the foreign partner authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. For further details, Swissmedic would refer readers to the authorisation of the foreign comparator product.
www.ema.europa.eu; www.fda.org
www.tga.gov.au

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Carbaglu®

Information for patients (package leaflet):
Information for patients Carbaglu®

Healthcare professionals (doctors, pharmacists) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.