

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

GLUCOSE COOPER 5% (glucose), glucose infusion

In paediatrics, no clinical benefit from a hypotonic glucose solution for injection outside its use as a vehicle for infusion therapy, because of the risk of severe or fatal hyponatraemia.

Main points

- ▶ Glucose-based medicinal products administered by injection have marketing authorisation:
 - as rehydration treatment when water loss is greater than loss of sodium chloride loss and other osmoles;
 - for the prevention of intra- and extracellular dehydration;
 - in the treatment and prevention of ketosis in undernourishment;
 - as a vehicle for administering therapies in the preoperative, perioperative and immediate postoperative period.
- ▶ The main benefit of a (hypotonic) 5% glucose solution for injection is its use as a vehicle for infusions of injectable medicinal products.
- ▶ **Hypotonic glucose solutions should be avoided in paediatrics to prevent encephalopathy caused by dilutional hyponatraemia.**

Therapeutic use

- The use of hypotonic solutions is associated with hyponatraemia-induced encephalopathy in children. According to recent international good practice guidelines on solutions for IV infusion in paediatrics, hypotonic solutions should not be used in children in a surgical context.

- **Role of the medicinal product in the therapeutic strategy**

The main benefit of a 5% glucose solution for injection (G5%) is its use as a vehicle for infusion therapy.

Rehydration and preventing dehydration: the administration of hypotonic 5% glucose solution for injection risks acute hyponatraemia in paediatric patients, with serious neurological complications that can lead to the patient's death. An isotonic solution (i.e. containing sodium chloride) is needed. Ready-to-use isotonic polyionic solutions are also available. The use of G5% "to keep vein open" should be prohibited in paediatrics. In adults, the risk of neurological complications is limited.

Prophylaxis and treatment of ketosis: glucose 5% solution for injection has a limited role in the therapeutic strategy, particularly in children. Oral feeding or enteral feeding at a constant flow rate provides more calories.

Clinical data

- The company has not provided any new clinical efficacy data.
- Several clinical studies have strongly suggested an increased risk of hyponatraemia when hypotonic solutions are administered to hospitalised patients with hypersecretion of antidiuretic hormone. Cases of acute (so-called dilutional) hyponatraemia causing encephalopathy have been reported in paediatrics; they have led to irreversible neurological complications and death.

Benefit of the medicinal product

- The actual clinical benefit* of GLUCOSE COOPER 5%, solution for injection remains substantial.
- Recommends continued inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.



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This document was created on the basis of the Transparency Committee Opinion of DD February 2017 (CT-15338) and is available at www.has-sante.fr

* The actual clinical benefit (ACB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the ACB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.