




EMLc

Codes ATC: H04AA01

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| Indication | Hypoglycaemia in the context of diabetes Code ICD11: 5A21.Z |
| INN | Glucagon |
| Type de médicament | Biological agent |
| Type de liste | Liste de base (EML) (EMLc) |
| Formulations | Parenteral > General injections > unspecified: 1 mg per mL |
| Historique des statuts LME | Ajouté pour la première fois en 2011 (TRS 965) |
| Sexe | Tous |
| Âge | Aussi recommandé pour les enfants |
| Équivalence thérapeutique | La recommandation concerne ce médicament spécifique |
| Renseignements sur le brevet | Patents have expired in most jurisdictions Lire la suite sur les brevets.  |
| Wikipédia | Glucagon  |
| DrugBank | Glucagon (Glucagon recombinant)  |

Résumé des preuves et recommandation du comité d'experts

An application was prepared by Daniel Agarwal, Dorothy Chyung, Brittany Carson, Lina Yi, Lena Makaroun, Rosa Kim, Sandeep Kishore, and Professor Marcus Reidenberg, Weill Cornell Medical College, New York, USA, for the inclusion of glucagon on the Model List. Listing was requested as an individual medicine. Expert reviews were prepared by Dr Lenita Wannmacher and Professor David Ofori-Adjei. Comments were received from Dr Shanti Mendis, Coordinator, Chronic Diseases Prevention and Management, WHO. The application provided evidence that hypoglycaemia is a common cause for admission to hospital for both adults and children in low-, middle-, and high-income settings (1-4) and the prevalence of hypoglycaemia in paediatric emergency presentations is up to 7.3% (5-7). The results of three studies (8-10) were provided to support the efficacy and safety of glucagon for the treatment of hypoglycaemia. The Committee noted that there were no RCTs comparing glucagon to alternative treatments for the management of hypoglycaemia. Glucagon appears to be well tolerated and can be used for the management of hypoglycaemia in adults, children, and pregnant women, however no evidence was identified for its use in neonates. The Committee also noted that glucagon has the advantage over 25% and 50% dextrose solutions as it can be given subcutaneously or intramuscularly, as well as in non-hospital settings for the treatment of hypoglycaemia in patients unable to ingest oral glucose due to impaired consciousness. The Committee noted that the cost of recombinant glucagon injection 1 mg/ml appears to be generally higher than 500 ml of 5% dextrose, but the price varies widely. The Committee concluded that the use of glucagon to treat hypoglycaemia is unlikely to be assessed in high-quality trials in the future, because it is relatively well established as a treatment in high-income countries and it is hard to determine what type of comparative trial could be approved ethically. Based on public health need, evidence of safety and efficacy, and the fact that inclusion in the Model List might push prices down, the Committee decided to add glucagon to the EML and the EMLc. The Committee particularly noted the increasing number of patients in developing countries needing treatment with insulin and the concerted efforts to improve access to such treatment in resource-constrained settings. The Committee therefore saw glucagon as a necessary adjunct to this effort, but recommended that careful attention be paid to the acquisition costs. The Secretariat was asked to amend the subheadings of the Lists accordingly. References: 1. Pal D et

al. Neonatal hypoglycaemia in Nepal 1. Prevalence and risk factors. Archives of Disease in Childhood, Fetal and Neonatal Edition, 2000, 82:F46–F51. 2. Güven M et al. Evaluation of patients admitted with hypoglycaemia to a teaching hospital in Central Anatolia. Postgraduate Medical Journal, 2000, 76:150–152. 3. Bassili A et al. The adequacy of diabetic care for children in a developing country. Diabetes Research and Clinical Practice, 2001, 53:187–199. 4. Wexler DJ et al. Prevalence of hyper- and hypoglycemia among inpatients with diabetes. Diabetes Care, 2007, 30(2):367–369. 5. Elusiyan JBE et al. Hypoglycaemia in a Nigerian paediatric emergency ward. Journal of Tropical Pediatrics, 2005, 52:96–102. 6. Osier FH et al. Abnormal blood glucose concentrations on admission to a rural Kenyan district hospital: prevalence and outcome. Archives of Disease in Childhood, 2003, 88:621–625. 7. Solomon T et al. Hypoglycaemia in paediatric admissions in Mozambique. The Lancet, 1994, 343:149–150. 8. Mühlhauser I, Koch J, Berger M. Pharmacokinetics and bioavailability of injected glucagon. Diabetes Care, 1985:39–42. 9. Casparie AE, Elving LD. Severe hypoglycemia in diabetic patients: frequency, causes, prevention. Diabetes Care, 1983, 8:141–145. 10. Collier A et al. Comparison of intravenous glucagon and dextrose in treatment of severe hypoglycemia in an accident and emergency department. Diabetes Care, 1987, 10:712–714.

