הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך: *15/03/16*

שם תכשיר באנגלית ומספר הרישום: Glucose 10%, 116-96-27991-00

שם בעל הרישום : Lapidot medical import and marketing LTD

טופס זה מפרט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
4.2 Posology and method of administration Dosage The dosage is to be adjusted according to the individual glucose and fluid requirements. ***Dosage for adults, the elderly and adolescents from 15 year of age*** The maximum daily dose is 40 ml per kg body weight (BW), corresponding to 4 g of glucose per kg BW. Note In the presence of metabolic disorders (e.g. postoperatively or after injuries, hypoxia, organ insufficiencies), the oxidative metabolism of glucose may be impaired. In such situations the glucose intake should be limited to 2 – 4 g/kg BW/day. The blood glucose level should not exceed 6.1 mmol/l (110 mg/100 ml). The maximum infusion rate is 2.5 ml per kg BW per hour, corresponding to 0.25 g of glucose per kg BW per hour. The maximum drop rate is 0.8 drops per kg BW per minute. Thus for a patient weighing 70 kg the maximum infusion rate is approx. 175 ml/hour (corresponding maximum drop rate 58 drops/min), resulting in a glucose intake of 17.5 g/hour. ***Dosage for Paediatric patients***	**Dosage** *Adults* The dosage depends on age, weight and clinical condition of the patient Maximum recommended dosage: 40 ml per kg body weight and per day, not more than 2000 ml per day. In case of insulin induced hypoglycemia determine blood glucose level before injecting dextrose. Flow rate: Up to 3.5 ml/kg body weight/h or (for 70 kg patient) up to 75 drops/min = 225 ml/h. *Children* According to individual requirements	**4.2 Posology and method of administration**

The daily dose is limited by the maximum fluid intake: 1st day of life: 50-70 ml per kg BW 2nd day of life: 70-90 ml per kg BW 3rd day of life: 80–100 ml per kg BW 4th day of life: 100–120 ml per kg BW From 5th day of life: 100–130 ml per kg BW 1st year: 100–140 ml per kg BW 2st year: 80–120 ml per kg BW 3rd –5th year: 80–100 ml per kg BW 6th –10th year: 60-80 ml per kg BW 11th –14th year: 50-70 ml per kg BW The corresponding glucose amounts are below the maximum recommended glucose doses for the respective age groups. If the solution is used as vehicle solution, a volume should be chosen that yields the desired concentration of the medicament to be dissolved or diluted. **Method of administration** Intravenous infusion. The solution can be administered peripherally. If 10 % w/v Glucose Intravenous Infusion is used as vehicle solution the possibility of peripheral infusion depends on the characteristics of the mixture prepared.	**Route of Administration** I.V.	
● Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour ● Decompensated diabetes mellitus, diabetic coma ● Untreated diabetes insipidus ● Acute states of shock and collapse ● Intracranial or spinal haemorrhage	● Hyperglycemia, ● Overhydration, ● Hypotonic dehydration, ● Acidosis, ● Hypokalemia, ● Diabetic coma while blood sugar is excessively high.	**4.3 Contraindications**

• Metabolic acidosis • Renal failure (oligo- or anuria) in absence of renal replacement therapy • Hyperhydration • Pulmonary oedema • Acute cardiac failure		

Administration of glucose solutions is not recommended after acute ischaemic strokes as hyperglycaemia was reported to worsen ischaemic brain damage and impair recovery. This solution should be used with caution in patients with hypervolemia, renal insufficiency and impending or manifest cardiac decompensation. The solution should also be administered with caution to patients with increased serum osmolarity. Disorders of fluid and electrolyte balance like hypotonic dehydration or pathologically low levels of serum electrolytes, must be corrected prior to administration of Glucose 10 % w/v solution for infusion. Special attention must be paid to hypokalaemia. Then supplementation of potassium is absolutely mandatory. Unstable metabolism (e.g. postoperatively or after injuries, hypoxia, organ insufficiencies) impairs oxidative metabolism of glucose and may lead to metabolic acidosis. States of hyperglycaemia should be adequetely monitored and treated with insulin. The application of insulin causes additional shifts of potassium into the cells and may therefore cause or increase hypokalaemia. Solutions containing glucose should be used with caution in patients with manifest or known subclinical diabetes mellitus or carbohydrate intolerance for any reason. Profound hypoglycemia may follow sudden discontinuation of high glucose infusion rates because of the accompanying high serum insulin concentrations. This applies especially to children less than 2 years of age, patients with diabetes mellitus and other disease states with impaired glucose homeostasis. In obvious cases the glucose infusion should be tapered off within the last 30 –60 minutes of the infusion. As a precaution it is	**warnings** Glucose injections should not be administered through the same infusion equipment, simultaneously, before, or after administration of blood, because of the possibility of pseudo-agglutination. This fluid should only be administered with great care to patients with diabetes mellitus or renal insufficiency. *Pregnancy* Safety for use during pregnancy has not been established. Use only when clearly needed and when the potential benefits outweigh the potential hazards to the fetus. *Children* Use with caution in infants of diabetic mothers, except as may be indicated in hypoglycemic neonates **Precautions** Hyperglycemia and glycosuria may be functions of rate of administration or metabolic insufficiency. To minimize these conditions, slow the infusion rate, monitor blood and urine glucose; if necessary, administer insulin. Administer so that extravasation does not occur. If thrombosis occurs during administration, stop infusion and correct. This fluid should only be administered with great care to patients with diabetes mellitus or renal insufficiency. Clinical supervision should include regular checks of blood glucose level, serum electrolytes and water balance. Electrolytes are to be supplemented as required. Caution is to be exercised in patients with hyponatremia. No other medication or substance should be	**4.4 Special warnings and precautions for use**

recommended that each individual patient be monitored for 30 minutes for hypoglycemia on the first day of abrupt discontinuation of parenteral nutrition. Refeeding or repletion of malnourished or depleted patients may in particular cause hypokalaemia, hypophosphataemia and hypomagnesaemia. Adequate supplementation of electrolytes according to deviations from normal values is necessary. Clinical monitoring should include blood glucose, serum electrolytes, fluid and acid-base balance in general. Frequency and kind of laboratory testing depend on the overall condition of the patient, the prevailing metabolic situation and the administered dose. Also monitor total volume and amount of glucose administered. Electrolytes and vitamins should be supplied as necessary. Vitamin B, especially thiamine, is needed for glucose metabolism. Glucose infusions should not be administered through the same infusion equipment, simultaneously with, before, or after administration of blood, because of the possibility of pseudo-agglutination.	added to this fluid, unless it is known to be compatible.	
Provided the product is used in accordance with the directions given, undesirable effects are not to be expected. The following side effects, which are not directly related to the product but to the conditions of administration, underlying disorders or accompanying treatment, may occur: Metabolism and nutrition disorders – Hypokalemia may be related to insulin therapy. In addition, hypokalaemia, hypomagnesaemia and hypophosphataemia may be caused by refeeding with glucose especially in malnourished patients.		**4.8 Undesirable effects**

– Abrupt discontinuation and/or insulin application may cause rebound hypoglycemia, especially in patients with glucose tolerance disorders. **Vascular disorders** Thrombophlebitis may be caused by osmolarities above 800 mmol/l. The osmolarity of the added medication should be kept in mind. **Reporting of suspected adverse reactions** Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Ministry of Health website by using an online form: https://forms.gov.il/globaldata /getsequence/getsequence.aspx ?formType=AdversEffect Medic@moh.health.gov.il		
Symptoms Overdose may cause hyperglycaemia, glucosuria, serum hyperosmolarity, possibly leading to hyperosmotic and hyperglycaemic coma, further hyperhydration and electrolyte disorders. Emergency treatment, antidotes The disorders mentioned above can be corrected by reduction of the glucose intake, administration of insulin and/or appropriate supplementation of electrolytes.	*Fluid/solute overload* Dextrose solutions I.V. can cause fluid or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states of pulmonary e~~dema.~~	**4.9 Overdose**
Single-dose container. Discard unused contents. Only to be used if the solution is clear and the container or its closure do not show		**6.6 Special precautions for disposal**

visible signs of damage.		

מצ״ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה (**ירוק**). יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט