הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך April, 2016

שם תכשיר באנגלית ומספר הרישום

Glucose 5% Intravenous Infusion BP (Viaflo®)

140 24 30797 00 ; 140 24 30797 01; 134 06 31397 00

שם בעל הרישום Teva Medical (Marketing) Ltd., Haorgim St 8, Ashdod 77100

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
Solution for infusion. Clear solution, free from visible particles. Osmolarity : 278 mOsm/l (approx.) pH : 3.5 – 6.5	Solution for infusion. Clear solution, free from visible particles	**Pharmaceutical Form**
		lndication
Glucose 5% intravenous infusion is an isosmotic solution. Please see section 3 for the information about the osmolarity of the solution. *Precautions to be taken before handling or administering the medicinal product* Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Electrolyte supplementation may be indicated according to the clinical needs of the patient. When introducing additives, the final osmolarity of solutions need to be checked. Administration of hyperosmolar solutions may cause venous irritation and phlebitis. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored. Please see section 4.4 for the risk of air embolism.	When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.	**Posology, dosage & administration**
Hypersensitivity to the active substance. See sections 4.4 and 4.8 for corn allergies.		**Contra-indications**
Dilution and other effects on serum electrolytes Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause: • Hyperosmolality, osmotic diuresis and dehydration • Hypoosmolality • Electrolyte disturbances such as - hyponatraemia (see below), - hypokalaemia, - hypophosphataemia, - hypomagnesaemia, - overhydration/hypervolaemia and, for example, congested states, including		**Special Warnings and Special Precautions for Use**

pulmonary congestion and oedema.

The above effects do not only result from the administration of electrolyte-free fluid but also from glucose administration.

Hyponatraemia can develop into acute hyponatraemic encephalopathy characterized by headache, nausea, seizures, lethargy, coma, cerebral oedema, and death.

Children, the elderly, women, postoperative patients, patients with hypoxia and patients with central nervous system disease or psychogenic polydipsia are at particular risk for this complication.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Particular caution is advised in patients at increased risk of water and electrolyte disturbances that could be aggravated by increased free water load, hyperglycaemia or possibly required insulin administration (see below).

Hyperglycaemia

- Rapid administration of glucose solutions may produce substantial hyperglycemia and a hyperosmolar syndrome.
- If hyperglycaemia occurs, rate of infusion should be adjusted and/or insulin administered
- If necessary, provide parenteral supplements in potassium.
- Intravenous Glucose 5% should be administered with caution in patients with, for example:
  - impaired glucose tolerance (such as in diabetes mellitus, renal failure, or in the presence of sepsis, trauma, or shock),
  - severe malnutrition (risk of precipitating a refeeding syndrome – see below),
  - thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due to impaired oxidative metabolization of pyruvate),
  - patients with ischemic stroke or severe traumatic brain injury
    Avoid infusion within the first 24 hours following head trauma. Monitor blood glucose closely as early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury.
  - newborns

Effects on Insulin Secretion

Prolonged intravenous administration of glucose and associated hyperglycaemia may result in decreased rates of glucose-stimulated insulin secretion.

Hypersensitivity Reactions

- Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported with Glucose solutions (see section 4.8). Solutions containing glucose should be used with caution, if at all, in patients with known allergy to corn or corn products. (see section 4.8).
- The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Refeeding syndrome

- Refeeding severely undernourished patients may result

in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Paediatric population

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy, and should be determined by a consulting physician experienced in paediatric intravenous fluid therapy.

In order to avoid potentially fatal over infusion of intravenous fluids to the neonate, special attention needs to be paid to the method of administration. When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe.

When using an infusion pump all clamps on the intravenous administration set must be closed before removing the administration set from the pump or switching the pump off. This is required regardless of whether the administration set has an anti free flow device.

The intravenous infusion device and administration equipment must be frequently monitored.

Paediatric hyponatraemia-related issues

- Children (including neonates and older children) are at increased risk of developing hypoosmotic hyponatraemia as well as for developing hyponatraemic encephalopathy.
- Plasma electrolyte concentrations should be closely monitored in the paediatric population.
- Rapid correction of hypoosmotic hyponataremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in paediatric intravenous fluid therapy.

Geriatric Use

- When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

Blood

- Glucose 5% (an aqueous, i.e., electrolyte-free glucose solution) should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because haemolysis and pseudoagglutination can occur.

Adding other medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Risk of Air Embolism

- Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.
- Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented

intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Both the glycaemic effects of Glucose 5% and its effects on water and electrolyte balance should be taken into account when using Glucose 5% in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.

Concomitant administration of catecholamines and steroids decreases the glucose up-take.

No interaction studies have been performed.

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Interaction with Other Medicaments and Other Forms of Interaction

When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation have to be considered separately.

Intrapartum maternal intravenous glucose infusion may result in foetal insulin production, with an associated risk of foetal hyperglycaemia and metabolic acidosis as well as rebound hypoglycaemia in the neonate.

Pregnancy
Glucose solution can be used during pregnancy. However, caution should be exercised when glucose solution is used intrapartum.

Fertility
There are no adequate data of the effect of Glucose 5% on fertility. However, no effect on fertility is expected.

Lactation
There are no adequate data of using Glucose solution during lactation. However, no effect on lactation is expected. Glucose 5% can be used during lactation.

Glucose solutions are commonly employed during pregnancy as hydrating fluids and as vehicles for the administration of other drugs (particularly for oxytocin).

There are no indications for adverse effects on progeny by use of Glucose 5% Intravenous Infusion during pregnancy, labour and lactation.

Fertility, Pregnancy and Lactation

Tabulated list of adverse reactions

System Organ Class	*Adverse reaction (MedDRA term)*	*Frequency*
Skin and subcutaneous tissue disorder	Rash	Not known
General disorders and administration site conditions	Chills* Pyrexia* Infusion site infection Infusion site irritation for example erythema Extravasation Local reaction Pain localised	Not known

~~Adverse reactions may be associated with the medicinal product added to the solution; the nature of the additive will determine the likelihood of any other undesirable effects.~~
~~In case of undesirable effect(s), the infusion must be discontinued.~~

Other adverse reactions reported with glucose injection/infusions include:
- Hyponatremia, which may be symptomatic

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of

Tabulated list of adverse reactions

System Organ Class	*Adverse reaction (MedDRA term)*	*Frequency*
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Adverse reactions may be associated with the medicinal product added to the solution; the nature of the additive will determine the likelihood of any other undesirable effects.
In case of undesirable effect(s), the infusion must be discontinued.

Adverse events

the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il		
Prolonged administration or rapid infusion of large volumes of Glucose 5% may cause hyperosmolarity and hyponatraemia, dehydration, hyperglycaemia, hyperglycosuria, osmotic diuresis (due to the hyperglycaemia) and water intoxication and oedema. Severe hyperglycaemia and hyponatraemia, may be fatal (see sections 4.4 and 4.8). In case of suspected overdose, treatment with Glucose 5% must be stopped immediately. Management of overdose is symptomatic and supportive, with appropriate monitoring.	Prolonged administration or rapid infusion of large volumes of glucose 5% solution may cause hyperosmolarity, dehydration, hyperglycaemia, hyperglycosuria, osmotic diuresis (due to the hyperglycaemia). Prolonged administration or rapid infusion may create a fluid inflation with oedema or water intoxication (with hyponatremia). The signs and symptoms of over infusion will be related to the nature of the additive being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant symptomatic and supportive measures should be provided as necessary.	**Overdosage**
Pharmacotherapeutic group: "Other IV Solution Additives" ATC code: B05BA03 The pharmacodynamic properties of this solution are those of glucose, which forms the principal source of energy in cellular metabolism. Glucose 5% is given as a source of carbohydrate in parenteral nutrition. The Glucose 5% solution provides a caloric intake of 200 kcal/l. Furthermore, this glucose solution for infusion allows hydric supplementation without ionic supplementation. Glucose 5% is an isosmotic solution, with an approximate osmolarity of 278 mOsm/l. The pharmacodynamics of the additive will depend on the nature of the drug used.	Pharmacotherapeutic group: "Other IV Solution Additives" ATC code: B05XX The pharmacodynamic properties of this solution are those of glucose, which forms the principal source of energy in cellular metabolism. Glucose is given as a source of carbohydrate in parenteral nutrition. The Glucose 5% solution provides a caloric intake of 200 kcal/l. Furthermore, this glucose solution for infusion allows hydric supplementation without ionic supplementation. Glucose 5% intravenous infusion is an isotonic solution, with an approximate osmolarity of 278 mOsm/l. The pharmacodynamics of the additive will depend on the nature of the drug used.	**Pharmaco-dynamic Properties**
Pack sizes: - 50 bags of 50 ml per carton - 75 bags of 50 ml per carton	Pack sizes: - 50 bags of 50 ml per carton	**Nature of contents of container**
Discard after single use. **Discard any unused portion.** **Do not store solutions containing additives.** **Do not reconnect partially used bags.** **Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.** **When introducing additives to Glucose 5% solution aseptic technique must be used.** **Mix the solution thoroughly when additives have been introduced.**	**Discard after single use.** **Discard any unused portion.** **Do not reconnect partially used bags.** **Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.**	**Special Precautions for Disposal and Other Handling Advice**