SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dextrose Vioser Solution for Infusion 5%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 55 mg glucose as glucose monohydrate
(Equivalent to 50 mg glucose anhydrous)
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless aqueous solution
Osmolarity: 278 mOsm/l
pH: 3.5 – 5.5

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Energy supply, hypertonic dehydration. Vehicle solution for supplementary medication.

4.2 Posology and method of administration

A volume that yields the desired concentration of the medicinal product for which Dextrose 5% is to be used as vehicle solution should be chosen, having regard to the maximum dose stated below.

Maximum daily dose
Up to 40 ml per kg body weight per day, corresponding to 2 g of glucose per kg body weight per day. For a 70 kg person this corresponds to a maximum infusion of 140.0 g/d of glucose, respectively 560 kcal. The maximum daily dose is in accordance with usual limitations of the daily fluid intake.

Maximum infusion and drip rate
The maximum infusion rate is 5 ml per kg body weight per hour, corresponding to 0.25 g (250 mg) of glucose per kg body weight per hour.
The maximum drip rate is 1.7 drops per kg body weight per minute.

Method of administration
Intravenous use. The solution must not be used if container or closure are damaged.
Solutions containing visible solid particles musts not be administered.
For single use only.
Partially used containers must not be reconnected.
After first use, the container and any unused contents should be discarded.

4.3 Contraindications

- Hypersensitivity to the active substance.
- Solutions containing dextrose may be contraindicated in patients with hypersensitivity to corn products.
- Hyperglycaemia,
- Hypokalaemia,
- Acidosis.

If it should be necessary to administer large volumes further contra-indications can arise on account of the glucose and/ or fluid load:
− Hyperhydration,
− Diabetic coma while blood sugar is excessively high,

4.4 Special warnings and precautions for use

Monitoring of blood glucose, fluid balance serum electrolytes, acid-base balance and serum potassium is necessary during administration of Dextrose Vioser Solution for Infusion 5%.
In patients with disturbed glucose metabolism, as present e.g. in postoperative or posttraumatic conditions, Dextrose 5% must be administered with care, i.e. under blood glucose monitoring, and dosage must be adapted in order to prevent physiological stress.
Dextrose 5% should only be administered with caution in patients with diabetes mellitus.
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.
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. When concentrated dextrose infusion is abruptly withdrawn, administer 5% dextrose to avoid hypoglycemic reactions. Administer so that extravasation does not occur. If thrombosis occurs during administration, stop infusion and correct.
Clinical supervision should include regular checks of blood glucose level, serum electrolytes and water balance. Electrolytes are to be supplemented as required.
Hypokalemia: Excessive administration of potassium free solutions may result in significant hypokalemia. Add potassium to dextrose solutions and administer to fasting patients with good renal function, especially those on digitalis therapy.
Vitamin B complex deficiency may occur with dextrose administration.
Caution is to be exercised in patients with hyponatremia. No other medication or substance should be added to this fluid, unless it is known to be compatible.

Warnings
This fluid should only be administered with great care to patients with renal insufficiency.
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 edema.
Hypertonic dextrose solutions may cause thrombosis if infused via peripheral veins, therefore, administer via a central venous catheter.
Diabetes mellitus: Use dextrose-containing solutions with caution in patients with sub-clinical or overt diabetes mellitus or carbohydrate intolerance.
Rapid administration of hypertonic solutions may produce significant hyperglycemia or hyperosmolar syndrome, especially in patients with chronic uremia or carbohydrate.
In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

Prolonged infusion of isotonic or hypotonic dextrose in water may increase the volume of extracellular fluid and cause water intoxication.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

Children
In neonates or in very small infants even small volumes of fluid may affect fluid and

electrolyte balance.
Care must be exercised in treatment of neonates, especially pre-term neonates, whose renal function may be immature and whose ability to excrete fluid and solute loads may be limited. Fluid intake, urine output, and serum electrolytes should be monitored closely. Serum glucose concentrations should be frequently monitored when dextrose is prescribed to pediatric patients, particularly infants, neonates, and low birth weight infants. Use with caution in infants of diabetic mothers, except as may be indicated in hypoglycemic neonates.

Geriatric Use
An evaluation of current literature revealed no clinical experience identifying differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
These drugs are known to be substantially excreted by the kidney, and the risk of toxic reactions to these drugs may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

4.5 Interactions with other medicinal products and other forms of interaction
None known

4.6 Pregnancy and lactation
For this medicinal product no restrictions of use during pregnancy and lactation are known.
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.
Lactation: Exercise caution when administrating dextrose to a nursing woman.
Labor and Delivery
As reported in the literature, dextrose solutions have been administered during labor and delivery. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations and acid base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

4.7 Effects on ability to drive and use machines
This medicinal product has no effect on ability to drive and use machines.

4.8 Undesirable effects
Febrile response; infection at the injection site; tissue necrosis; venous thrombosis or phlebitis extending from the site of the injection; extravasation; hypovolemia, hypervolemia; dehydration; mental confusion or unconsciousness. These may occur because of the solution of administration technique. Use the largest available peripheral vein and a well placed small bore needle. Too rapid infusion of hypertonic solutions may cause local pain and venous irritation. Rate of administration should be adjusted according to tolerance.
Hypertonic solutions are more likely to cause irritation; administer into larger central veins. Significant hyperglycemia, hyperosmolar syndrome and glycosuria may occur with too rapid administration of hypertonic solutions.
The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form www.sideeffects.health.gov.il and emailed to the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

4.9 Overdose

Symptoms

Overdose may result in hyperhydration, electrolyte and acid-base imbalances, hyperglycaemia, glucosuria and serum hyperosmolarity, up to hyperglycaemic hyperosmotic coma. Emergency treatment, antidotes.

In case of overdose, the infusion should be discontinued, and electrolytes, diuretics, or insulin should be administered depending on type and severity of the symptoms.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Solvents and diluting agents incl. irrigating solutions

ATC code: V07AB

Low concentration glucose solutions are suitable diluents for active substances because glucose, as a natural substrate of the cells in the organism, is ubiquitously metabolized. Under physiological conditions glucose is the most important energy-supplying carbohydrate with a caloric value of 17 kJ/g or 4 kcal/g. In adults, the normal concentration of glucose in blood is reported to be 60 – 100 mg/100 ml, or 3.3 – 5.6 mmol/l (fasting).

5.2 Pharmacokinetic Properties

On infusion glucose is first distributed in the intravascular space and then is taken up into the intracellular space.

In glycolysis glucose is metabolized to pyruvate or to lactate. Lactate can be partially re-introduced into the glucose metabolism (CORI cycle). Under aerobic conditions pyruvate is completely oxidized to carbon dioxide and water. The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water).

5.3 Preclinical Safety Data

No preclinical studies on toxicity and safety pharmacology have been conducted with Dextrose 5%.

Since glucose is a natural substrate of human metabolism, Dextrose 5% is not expected to have toxic effects when used as directed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection.

6.2 Incompatibilities

Because Dextrose 5% has an acid pH, incompatibilities can occur on mixing with other medicinal products.

Erythrocyte concentrates must not be suspended in Dextrose 5% because this can lead to pseudo-agglutination.

Glucose solutions should not be infused through the same equipment as blood, see section 4.4.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25 °C.

6.5 Nature and contents of container

100 ml, 250 ml, 500 ml and 1000 ml LDPE bottles.
Each pack contains 10 bottles.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Containers are for single use only. After use, the container and any residual content should be discarded (see also section 4.2).

7 MANUFACTURER

Vioser S.A. Parenteral Solutions Industry 9TH KM National Road Trikala-Larisa, Taxiarches Trikala, 42100, Greece

8 LICENSE HOLDER

Eldan Electronic Instruments CO Ltd.
Ha-Shiloah 6, POB 7641, Petach Tiqva 4917001, Israel

9 LICENSE NUMBER

169-12-36112

Revised in August 2022 according to the MOH guidelines.