הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך: 14.01.2017

שם תכשיר באנגלית: Dextrose 5% and Sodium Chloride 0.45% Injection

מספר רישום: 038 88 22826 00

שם בעל הרישום: Teva Medical LTD

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
Contraindications		Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products

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.		**PRECAUTIONS**
Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection. **Carcinogenesis, mutagenesis, impairment of fertility** Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility. **Pregnancy: Teratogenic Effects** Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also not known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed. **Labor and Delivery** Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery. **Nursing Mothers** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection is administered to a nursing mother. **Pediatric Use** The use of Dextrose and Sodium Chloride Injection, USP in pediatric patients is based on clinical practice. Newborns - especially those born premature and with low birth weight - are at increased risk of developing hypo - or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death. Plasma electrolyte concentrations should be closely monitored		**Drug Interactions**

in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes. The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency (applies to solutions containing less than 0.9% Sodium Chloride). **Geriatric Use** Clinical studies of Dextrose and Sodium Chloride Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between 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. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug 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.		

- Hypersensitivity reactions, including anaphylaxis and chills - Hyponatremia		**ADVERSE REACTIONS**
As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact. All injections plastic containers are intended for intravenous administration using sterile equipment. The dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia. The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy. ~~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.~~ ~~Vitamin B complex deficiency may occur with dextrose administration~~ Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.		**DOSAGE AND ADMINISTRATION**