הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך: 05.02.2017

שם תכשיר באנגלית: Sodium Chloride 0.45% Injection

מספר רישום: 041-21-23285-00

שם בעל הרישום: Teva Medical LTD

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

פרק בעלון	טקסט נוכחי	טקסט חדש
warnings		Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus may occur with 0.45% Sodium Chloride Injection. Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated. Depending on the volume and rate of infusion, the intravenous administration, 0.45% Sodium Chloride Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration/hypervolemia, congested states, pulmonary edema, or acid-base imbalance. The risk of dilutive states is inversely proportional to the electrolyte concentration of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection. 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. The infusion of solutions with 0.45% Sodium Chloride Injection may result in hyponatremia. Close clinical monitoring may be warranted. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death. The risk for hyponatremia is increased, for example, in children, elderly, women, postoperatively, in persons with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as certain antiepileptic and psychotropic medications). The risk for developing hyponatremic encephalopathy is increased, for example, in pediatric patients (<16 years of age), women

(in particular pre-menopausal women), in patients with hypoxemia, and in patients with underlying central nervous system disease. Acute symptomatic hyponatremic encephalopathy is considered a medical emergency. Administer of 0.45% Sodium Chloride Injection, with particular caution to patients with or at risk for hypervolemia or with conditions that may cause sodium retention, fluid overload and edema; such as patients with primary hyperaldosteronism, or secondary hyperaldosteronism [e.g., associated with hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis) or pre-eclampsia]. Certain medications may increase risk of sodium and fluid retention, see DRUG INTERACTIONS. ADMINISTER of 0.45% Sodium Chloride Injection with particular caution to patients with severe renal impairment. In such patients, administration of Sodium Chloride Injection, may result in sodium retention.		

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. Do not mix or administer 0.45% Sodium Chloride Injection through the same administration set with whole blood or cellular blood components. Rapid correction of hypo- and hypernatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in intravenous fluid therapy.		**PRECAUTIONS**
Pregnancy Category C There are no adequate and well controlled studies with 0.45 % Sodium Chloride Injection in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Sodium Chloride Injection, can cause fetal harm when administered to a pregnant woman. 0.45% Sodium Chloride Injection should be given during pregnancy only if only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers** It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when 0.45% Sodium Chloride Injection is administered to a nursing woman.		**Pregnancy**
The use of 0.45 %Sodium Chloride Injection in pediatric patients is based on clinical practice. (See DOSAGE AND ADMINISTRATION). Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes. The infusion of hypotonic fluids (0.45% Sodium Chloride Injection) 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 edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency.		**Pediatric Use**

Clinical studies of 0.45% 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.		**Geriatric Use**
The following adverse reactions have been identified during post-approval use of Sodium Chloride Injections. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Hyponatremia has been reported for 0.45% Sodium Chloride Injection (see Pediatric Use section). The following adverse reactions have not been reported with 0.45% Sodium Chloride Injection but may occur: hyperchloremic metabolic acidosis, hypersensitivity/infusion reaction (including hypotension, pyrexia, tremor, chills, urticaria, rash and pruritus), and infusion site reactions (such as infusion site erythema, injection site streaking, burning sensation, infusion site urticaria).		**ADVERSE REACTIONS**
Excessive administration of 0.45% Sodium Chloride Injection may lead to hyponatremia and hypernatremia. Both hyponatremia and hypernatremia can lead to CNS manifestations, including seizures, coma, cerebral edema and death. Excessive administration of 0.45% Sodium Chloride Injection may lead to sodium overload (which can lead to central and/or peripheral edema). When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment.		**OVERDOSAGE**

When other electrolytes or medicines are added to this solution, the dosage and the infusion rate will also be dictated by the dose regimen of the additions. Additives may be incompatible with 0.45% Sodium Chloride Injection. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Sodium Chloride Injection, is appropriate. After addition, check for unexpected color changes and/or the appearance of precipitates, insoluble complexes or crystals. The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible must not be used. When introducing additives to Sodium Chloride Injection, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.		**DOSAGE AND ADMINISTRATION**