הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך ____July 9, 2015 _____

שם תכשיר באנגלית ומספר הרישום

Sodium Chloride 0.9% Intravenous Infusion BP (Viaflo®) Container _

140 26 30794 00 ; 140 26 30794 01; 134 05 31396 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
		Indication
		Contra-indications
The ~~concentration and~~ dosage, rate and duration of ~~sodium chloride solution for intravenous use~~ administration is to be individualized as determined by several factors including ~~the~~ age, weight, ~~and~~ clinical condition, concomitant treatment ~~of the patient~~ and in particular the patient's hydration state, clinical and laboratory response to treatment. Fluid balance and plasma electrolyte concentrations must be monitored during treatment. ~~Serum-electrolyte concentrations should be carefully monitored.~~ *Recommended dosage* The recommended dosage for treatment of isotonic extracellular dehydration and sodium depletion is: - for adults : 500 ml to 3 liters /24h - for babies and children : 20 to 100 ml per 24 h and per kg of body weight, depending on the age and the total body mass. ~~The infusion rate depends on the patient clinical condition.~~ Method of administration **The solution is for administration by intravenous infusion through a sterile and non-pyrogenic administration set, using aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.** The product should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless solution is clear, free from visible particles and the seal is intact Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the solution. Administer immediately following the insertion of infusion set. Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. 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. Additives may be introduced before infusion or during infusion through the injection site.	The concentration and dosage, of sodium chloride solution for intravenous use is determined by several factors including the age, weight, and clinical condition, of the patient and in particular the patient's hydration state, clinical and laboratory response to treatment.. Serum-electrolyte concentrations should be carefully monitored. Recommended dosage The recommended dosage for treatment of isotonic extracellular dehydration and sodium depletion is: - for adults : 500 ml to 3 liters /24h - for babies and children : 20 to 100 ml per 24 h and per kg of body weight, depending on the age and the total body mass. The infusion rate depends on the patient clinical condition. Method of administration The solution is for administration by intravenous infusion	**Posology, dosage & administra-tion**

For information on incompatibilities and preparation of the product (with additives), please see sections 6.2 and 6.6.		
Fluid balance/renal function *Use in patients with (severe) renal impairment* Sodium Chloride 0.9% should be administered with particular caution, to patients with or at risk of severe renal impairment. In such patients administration of Sodium Chloride 0.9% may result in sodium retention. (See "Use in patients at risk for sodium retention, fluid overload and oedema" below; for additional considerations.) *Risk of fluid and/or solute overload and electrolyte disturbances* Depending on the volume and rate of infusion, intravenous administration of Sodium Chloride 0.9% can cause: • Fluid and/or solute overload resulting in overhydration/hypervolemia and, for example, congested states, including central and peripheral oedema. • Clinically relevant electrolyte disturbances and acid-base imbalance. In general, the risk of dilutional states is inversely proportional to the electrolyte concentrations of Sodium Chloride 0.9% and its additions. The risk of solute overload causing congested states is directly proportional to the electrolyte concentrations of Sodium Chloride 0.9% and its additions. Special clinical monitoring is required at the beginning of any intravenous infusion. 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. ~~*Administration should be carried out under regular and careful surveillance. Clinical and biological parameters, in particular serum electrolytes, should be monitored.*~~ *Use in patients at risk for sodium retention, fluid overload and oedema* *Use in patients at risk for sodium retention, fluid overload and oedema* Sodium Chloride 0.9% should be used with particular caution, if at all, in patients with or at risk for: Hypernatraemia. Rapidly correcting hypernatraemia once adaptation has occurred may lead to cerebral oedema, potentially resulting in seizures, permanent brain damage, or death. • Hyperchloraemia • Metabolic acidosis, which may be worsened by prolonged use of this product, especially in patients with renal impairment. • Hypervolaemia such as congestive heart failure and pulmonary oedema may be precipitated, particularly in patients with cardiovascular disease. • Iatrogenic hyperchloraemic metabolic acidosis (e.g., during intravenous volume resuscitation) • Conditions that may cause sodium retention, fluid overload and oedema (central and peripheral), such as patients with o primary hyperaldosteronism, o secondary hyperaldosteronism, associated with, for example, - hypertension, - congestive heart failure, - liver disease (including cirrhosis),	Special clinical monitoring is required at the beginning of any intravenous infusion. Administration should be carried out under regular and careful surveillance. Clinical and biological parameters, in particular serum-electrolytes, should be monitored. For information on preparation of the product and additives, please see section 6.6. Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusions of sodium chloride should therefore only be given after determination of the serum sodium level. Sodium chloride must be used with caution to patients with hypertension, heart failure, peripheral or pulmonary edema, impaired renal function, pre-eclampsia, aldosteronism, or other conditions and treatment (e.g. corticosteroids) associated with sodium retention.	**Special Warnings and Special Precau-tions for Use**

- renal disease (including renal artery stenosis, nephrosclerosis) or pre-eclampsia. Medications that may increase the risk of sodium and fluid retention, such as corticosteroids *Infusion reactions* Symptoms of unknown aetiology which can appear to be hypersensitivity reactions have been reported very rarely in association with infusion of Sodium Chloride 0.9 %. These have been characterized as hypotension, pyrexia, tremor, chills, urticaria, rash and pruritus. Stop the infusion immediately if signs or symptoms of these reactions develop. Appropriate therapeutic countermeasures should be instituted as clinically indicated. **Specific patient groups** The consulting physician should be experienced in this product's use and safety in these special populations that are especially sensitive to rapid changes in serum sodium levels. Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurologic complications). See section "Hyponatraemia/hypernatraemia" above. *Paediatric population* Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes. Repeated infusions of sodium chloride should therefore only be given after determination of the serum sodium level. *Geriatric population* 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. For information on preparation of the product and additives, please see section 6.6. ~~Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusions of sodium chloride should therefore only be given after determination of the serum sodium level.~~ ~~Sodium chloride must be used with caution to patients with hypertension, heart failure, peripheral or pulmonary edema, impaired renal function, pre-eclampsia, aldosteronism, or other conditions and treatment (e.g. corticosteroids) associated with sodium retention.~~		
		Precau-tions
Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Sodium Chloride 0.9%. Administration of Sodium Chloride 0.9% may result in decreased lithium levels. Corticoids/Steroids and carbenoxolone, are associated with the retention of sodium and water (with oedema and hypertension). See Section 4.4 Special warnings and precautions for use. ~~Corticosteroids are associated with the retention of sodium and water, with edema and hypertension. Disturbances of electrolyte balance are common with naturally occurring corticosteroids such as cortisone and hydrocortisone, but are less frequent with many synthetic glucocorticoids, which have little or no mineralocorticoid activity.~~	Corticosteroids are associated with the retention of sodium and water, with edema and hypertension. Disturbances of electrolyte balance are common with naturally occurring corticosteroids such as cortisone and hydrocortisone, but are less frequent with many synthetic glucocorticoids, which have little or no mineralocorticoid activity.	**Inter-action with Other Medica-ments and Other Forms of Inter-action**

There are no adequate data from the use of Sodium Chloride 0.9% in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride 0.9%. When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation has to be considered separately.

~~Sodium Chloride infusion has been used in pregnant women, however no specific data is available on the use of Sodium Chloride infusion in pregnancy and lactation.~~

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Fertility, pregnancy and Lactation

No studies have been conducted on the influence of Sodium Chloride 0.9% on the ability to operate an automobile or other heavy machinery.

~~None known.~~

None known.

Effects on the ability to drive and use machines

The following adverse reactions have been reported in post-marketing experience. The frequency of the adverse drug reactions listed in this section cannot be estimated from the available data.

System Organ Class (SOC)	Adverse reactions (Preferred Term)	Frequency
Nervous system disorders	Tremor	Not known
Vascular disorders	Hypotension	Not known
Skin and subcutaneous tissue disorders	Urticaria Rash Pruritus	Not known
General disorders and administration site conditions	Infusion site reactions, such as • Infusion site erythema, • Injection site • streaking, burning sensation, • , Infusion • site urticaria • Pyrexia • Chills	Not known

The following adverse reactions have not been reported with this product but may occur:

- Hypernatraemia (eg. when administered to patients with nephrogenic diabetes insipidus or high nasogastric output)

- Hyperchloraemic metabolic acidosis
- Hyponatraemia, which may be symptomatic. Hyponatraemia may occur when normal free water excretion is impaired. (eg SIADH or postoperative

~~Undesirable effects are not expected in the usual treatment conditions.~~
~~Adverse reactions may be associated to the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous~~

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Adverse reactions may be associated to the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.
Rare case of central pontine myelinolysis (a potentially severe or lethal demyelinating disorder to the central nervous system) have been reported.

Additives

When sodium chloride 0.9% is used as a diluent for injectable preparations of other drugs, the nature of additives will determine the likelihood of any other undesirable effect.

If an adverse reaction to the added medicinal product does occur, discontinue the infusion, e, institute appropriate counter measures be started, if needed the infusion should be stopped. The remaining part of the solution should be kept for investigation if deemed necessary.

Adverse events

~~thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.~~ ~~Rare case of central pontine myelinolysis (a potentially severe or lethal demyelinating disorder to the~~ *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 . according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx ?formType=AdversEffectMedic@moh.health.gov.il) or by email (adr@MOH.HEALTH.GOV.IL). ~~central nervous system) have been reported.~~ *Additives* When sodium chloride 0.9% is used as a diluent for injectable preparations of other drugs, the nature of additives will determine the likelihood of any other undesirable effect. If an adverse event occurs ~~reaction to the added medicinal product does occur~~, ~~discontinue the infusion, evaluate~~ the patient should be evaluated and, ~~institute~~ appropriate counter measures be started, if needed the infusion should be stopped. The remaining part of the solution should be kept ~~and save the remainder of the fluid~~ for investigation ~~examination~~ if deemed necessary. ~~Undesirable effects are not expected in the usual treatment conditions.~~ ~~Adverse reactions may be associated to the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.~~ ~~Rare case of central pontine myelinolysis (a potentially severe or lethal demyelinating disorder to the~~		
An excessive volume of Sodium Chloride 0.9% may lead to hypernatraemia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema and death) and sodium overload (which can lead to central and/or peripheral oedema) and should be treated by an attending specialised physician. ~~Excessive administration of sodium chloride may cause hypernatremia and should be treated by an attending specialised physician.~~	Excessive administration of sodium chloride may cause hypernatremia and should be treated by an attending specialised physician.	**Overdosage**
As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition. In the absence of compatibility studies, this solution must not be mixed with other medicinal products. Those additives known to be incompatible should not be used. See section 6.6 for further instructions on the use of the product with additives. ~~It is the responsibility of the physician to judge the~~	As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition. It is the responsibility of the physician to judge the incompatibility of an additive medication with the Sodium Chloride 0.9% Intravenous Infusion solution by checking for eventual color change and/or eventual	**Incompa-tibilities**

~~incompatibility of an additive medication with the Sodium Chloride 0.9% Intravenous Infusion solution by checking for eventual color change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted.~~ ~~Before adding a drug, verify:~~ ~~- It is soluble and stable in water at the pH range of the Sodium Chloride 0.9% Intravenous Infusion solution~~ ~~When a compatible medication is added to the Sodium Chloride Intravenous Infusion, the solution must be administered immediately.~~ ~~Those additives known to be incompatible should not be used.~~	precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted. Before adding a drug, verify: - It is soluble and stable in water at the pH range of the Sodium Chloride 0.9% Intravenous Infusion solution When a compatible medication is added to the Sodium Chloride Intravenous Infusion, the solution must be administered immediately. Those additives known to be incompatible should not be used.	
Please see section 4.2 for information regarding the method of administration. Before adding a drug, verify it is soluble and stable in water at the pH range of the Sodium Chloride 0.9% Intravenous Infusion solution. Additives may be introduced before infusion or during infusion through the injection site. It is the responsibility of the physician to judge the incompatibility of an additive medication with the Sodium Chloride 0.9% Intravenous Infusion solution by checking for eventual color change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted. ~~Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.~~ ~~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.~~ ~~The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.~~ ~~Additives may be introduced before infusion or during infusion through the injection site.~~	Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set. 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. The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system. Additives may be introduced before infusion or during infusion through the injection site.	**Special precautions for disposal and other handling advice**