תאריך: אפריל 2020

רופא/ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

Sodium Chloride 0.9% Intravenous Infusion BP

סודיום כלוריד 0.9 % לעירוי לתוך הוריד

Contains: Sodium Chloride: 9.00 g/l

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

Sodium Chloride 0.9% intravenous infusion is indicated for:

- Treatment of isotonic extracellular dehydration
- Treatment of sodium depletion

Vehicle or diluent of compatible drugs for parenteral administration

<u>ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום):</u>

4.4. Special warnings and precautions for use

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia (see below).

Hyponatraemia
Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, cerebral contusion and brain oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

This medicinal product contains 354 mg sodium per 100 ml, equivalent to 17.7% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5.Interaction with other medicinal products and other forms of interaction

Drugs leading to an increased vasopressin effect
The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.4 and 4.8).

- Drugs stimulating vasopressin release include: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues include: Desmopressin, oxytocin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

4.6. Fertility, pregnancy and lactation

Sodium Chloride 0.9% should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin (see section 4.4, 4.5 and 4.8).

4.8.Undesirable effects

System Organ Class (SOC)	Adverse reactions (Preferred Term)	Frequency
Nervous system disorders	Tremor Acute hyponatraemic encephalopathy*	Not known
Metabolism and nutrition disorders	Hospital acquired hyponatraemia*	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, • Vein irritation, Injection site streaking, burning sensation, • Local pain or reaction , Infusion site urticaria • Infection at the site of injection, • Venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia • Pyrexia • Chills	Not known

*Hospital acquired hyponatraemia may cause irreversible brain injury and death, due to development of acute hyponatraemic encephalopathy, frequency unknown (see sections 4.4, 4.5).

6. PHARMACEUTICAL PARTICULARS

6.3.Shelf life

Shelf life as packaged:

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