

02/2023

SODIUM CHLORIDE VIOSER SOLUTION 0.9%

סודיום כלוריד ויוסר תמיסה 0.9%

מרכיבים פעילים: SODIUM CHLORIDE 9 MG/ML

צורת מינון ומתן: Solution - I.M , I.V , S.C , EXTERNAL

רופא/ה, רוקח/ת נכבד/ה,
חברת אלדן ציוד אלקטרוני בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.
העלון עודכן בתאריך פברואר 2023.

ההתוויות הרשומות לתכשיר בישראל:

- Short-term intravascular volume substitution.
- Hypotonic dehydration or isotonic dehydration.
- Vehicle solution for supplementary medication.
- Fluid and electrolyte replacement, hypochloremic alkalosis and chloride losses.
- Externally for wound irrigation and moistening of wound tamponades dressing.

בהודעה זו מצוינים השינויים המהותיים בלבד.

מקראה לעדכונים המסומנים:

מידע שהוסר - מסומן בקו אדום חוצה **XXX**
תוספת - כתב **כחול**

עדכונים מהותיים נעשו בסעיף הבא בעלון לרופא:

6.2 Incompatibilities

~~Possible incompatibilities are to be borne in mind when mixed with other medicinal products.~~

As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition. In the absence of compatibility studies, this medicinal product 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.

6.6 Special precautions for disposal

~~The containers are intended for single use only. After administration, the container and any remaining solution are to be discarded.~~

Use only if the solution is clear, without visible particles and if the container is undamaged.

Administer immediately following the insertion of infusion set.

Before adding a drug, verify it is soluble and stable in water at the pH range of Sodium Chloride Vioser Solution 0.9%. Additives may be introduced before infusion through the injection site.

It is the responsibility of the physician to judge the incompatibility of an additive medication with Sodium Chloride Vioser Solution 0.9% by checking for eventual colour change and/or eventual precipitate, insoluble complexes or crystals apparition .

When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.





Discard after single use.

Discard any unused portion.

Do not reconnect partially used containers.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Instructions for use

- Check for minute leaks by squeezing container firmly. If leaks are found, discard solution, as sterility may be impaired.
- Check solution for limpidity and absence of foreign matter. If solution is not clear or contains foreign matter, discard the solution.
- Each plastic bottle has a protective cap. The protective ring is removed just before use with a simple pull and the infusion device is adjusted in the special elastic slot. Administer immediately following the insertion of infusion set.

Preparation for administration

Use sterile material for preparation and administration.

- Suspend container from eyelet support.
- Remove plastic protector from outlet port at bottom of container.
- Use an aseptic method to set up the infusion.
- Attach administration set. Refer to directions of the accompanying set for connection, priming of the set and administration of the solution.

Techniques for injection of additive medications

Warning: Additives may be incompatible.

To add medication before administration:

- Disinfect medication site.
- Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture medication port and inject.
- Mix solution and medication thoroughly.

Caution: Do not store bags containing added medications.

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום אלדן ציוד אלקטרוני בע"מ, בנין ניאופרם, רחוב השילוח 6 ת.ד. 7641 פתח תקוה 4917001.

בברכה

עדי חלוצי

רוקחת ממונה

