B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

NaCl Bernburg 9 mg/ml solution for injection/infusion and irrigation solution

2. Composition

Each ml contains:

Sodium chloride 9 mg

Clear, colourless particle free solution

3. Target species

Cattle, horses, sheep, goats, pigs, dogs, cats, rabbits and guinea pigs.

4. Indications for use

Correction of sodium imbalances.
Treatment of metabolic alkalosis, during as well as after surgery.
Rehydration in disease conditions which result in excessive loss of water and sodium and sodium chloride, as well as during and after surgery.
Vehicle for the administration of other compatible drugs.
Externally for irrigation of wounds and moisturizing of dressings.

5. Contraindications

Do not use in
- animals with sodium and water retention, especially in heart failure,
- animals with hypernatremia, hyperchloraemia, hyperhydration,
- animals suffering from oedema (hepatic, renal or cardial).

6. Special warnings

Special precautions for safe use in the target species:
The solution should be warmed up to body temperature of target animal species to avoid hypothermia.

The volume and infusion rate must be adapted to age, weight and the clinical status of each animal.

Serum electrolyte levels, water and acid-base balance, and the clinical condition of the animal must be closely monitored during treatment to prevent overdose, especially in the event of changes in metabolism or kidney function. The veterinary medicinal product should not be used for longer than is necessary to correct and maintain the circulating volume. The electrolyte composition of the solution is not adequately balanced for long-term hydration to meet maintenance needs. Inappropriate or excessive use may exacerbate or cause metabolic acidosis.

Ensure that the solution is clear and contains no visible particles and the unit is perfectly intact.
Otherwise, do not use the solution. Discard any unused portion. Do not reuse a partially used bag.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
It is recommended to take appropriate precautions in animals receiving corticosteroids or ACTH to prevent high blood pressure and excessive fluid retention when administering large volumes. Concomitant administration of colloids requires dose reduction.
No other drug interactions are known.

Overdose:
It is recommended to maintain a serum sodium less than or equal to 130 mEq/l. In the presence of volume overload signs, the infusion should be stopped and an adequate diuretic should be administered.

Major incompatibilities:
No compatibility studies have been conducted.

The characteristics of any drug diluted with the product must be carefully controlled. Please monitor for a colour change or any appearance of a precipitate of insoluble complexes or crystals. Reference should be made to the summary of product characteristics of the drug being co-administered for incompatibilities information.

Before adding a drug, verify it is soluble in water at the pH of the product.

Unless a clear recommendation on the stability of the diluted product is available in the summary of product characteristics of the drug being co-administered, any drug diluted with the product should be used immediately.

7. Adverse events

Cattle, horses, sheep, goats, pigs, dogs, cats, rabbits and guinea pigs:

Not known under normal conditions of use.

Undetermined frequency:	Circulatory overload*

*caused by excessive speed and volume of infusion

Where the product is used as a drug carrier, this can lead to other adverse effects.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder < or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Slow intravenous infusion; intravenous, subcutaneous or intraperitoneal injection; cutaneous use.

When given subcutaneously, reduced doses are recommended.

The amount of fluid and electrolytes to be administered should be calculated by adding the existing deficits to the ongoing maintenance requirements and any ongoing fluid losses (e.g. from vomiting, diarrhoea etc.) estimated from the history of the animal, clinical examination and laboratory findings.

To calculate the existing fluid deficit, the following equation should be used:
Fluid deficit (ml) = Percentage dehydration x Bodyweight (kg) x 10
(e.g. for a 10 kg dog with 5 % dehydration the fluid deficit would be 5 x 10 x 10 = 500 ml)

To calculate the ongoing crystalloid maintenance requirement, the following equation should be used:
Maintenance per day for Cattle, Horses, Sheep, Goats, Pigs, Dogs and Cats (ml) = 50 ml x Bodyweight (kg)
(e.g. for a 10 kg dog, the daily maintenance fluid requirement is 10 x 50 = 500 ml)
Maintenance per day for Rabbits (ml) = 75 - 100 ml x Bodyweight (kg)
Maintenance per day for Guinea Pig (ml) = 50 - 60 ml x Bodyweight (kg)

Maximum subcutaneous bolus injection for guinea pig is 20 ml/ kg Bodyweight.

The administration rate should be adjusted to each animal. The objective is to correct the deficit over 12 - 24 hours.

9. Advice on correct administration

Please refer to section on "Dosage for each species, routes and method of administration".

10. Withdrawal periods

Cattle, horses, sheep, goats, pigs, rabbits:
Meat and offal: zero days.
Milk: zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA-No.: To be completed nationally.

Package sizes:
1 x 500 ml
10 x 500 ml

20 x 500 ml
10 x 1000 ml
1 x 5000 ml
2 x 5000 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

mm/yyyy

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:
Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany
Tel: +49 (0)3471 860 4300

<Local representatives <and contact details to report suspected adverse reactions>:
To be completed nationally.