ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Sodium chloride 9 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

Clear, colourless particle free solution

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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.

3.3 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).

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QB05BB01

4.2 Pharmacodynamics

Sodium chloride and water are normal constituents of the plasma of animals.

4.3 Pharmacokinetics

Sodium chloride administered by the intravenous route quickly joins the normal distribution and metabolism of sodium chloride and water, in the intracellular and extracellular spaces.

5. PHARMACEUTICAL PARTICULARS

5.1 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.

5.2 Shelf life

500 ml/5000 ml bags: Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

500 ml/1000 ml bottles: Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

500 ml: Polypropylene (PP) bag with polycarbonate cone, butyl rubber stopper and bordered aluminium/polypropylene cap, overwrapped in polypropylene foil.

5000 ml: Polyvinylchloride (PVC) bag with polycarbonate cone, butyl rubber stopper and bordered aluminium/polypropylene cap, overwrapped in polyamide/polypropylene foil.

500 ml and 1000 ml: Polyethylene (PE) bottles with polyethylene twin port cap containing an elastomeric disc made of styrene copolymer.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD month YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

mm/yyyy

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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