1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 1 (9 mg/ml) solution for infusion for cattle, horses, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Sodium Chloride 9 mg

Sodium: 150 mmol/litre
Chloride: 150 mmol/litre

Excipient:

Qualitative composition of excipients and other constituents
Water for injections

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs and cats.

3.2 Indications for use for each target species

For the treatment of dehydration in cattle, horses, dogs and cats. It may be used to correct hypovolaemia resulting from shock or gastrointestinal disease (especially where metabolic alkalosis is present, e.g. in cases of sustained vomiting or abomasal disorders in cattle). It may be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally.

3.3 Contraindications

Do not use in animals with:
- hypernatraemia
- hyperchloraemia
- hyperhydration
- oedema (hepatic, renal, or cardiac).

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not use unless the solution is clear, free from visible particles and the container is undamaged.
Sodium overload may occur in animals with cardiac or renal impairment. It should be noted that sodium excretion may be impaired post-surgery/trauma.
A risk of thrombosis with intravenous infusion should be considered.

Maintain aseptic precautions.
The veterinary medicinal product should be warmed to approximately 37 °C prior to the administration of large volumes, or if the administration rate is high, in order to avoid hypothermia.
Use with caution in animals with hypokalaemia.
Serum electrolyte levels, water and acid-base balance and the clinical condition of the animal should be closely monitored during the treatment in order to prevent overdose, particularly in cases of renal or metabolic changes.
This veterinary medicinal product should not be used for longer than is necessary to correct and sustain circulating volume. This solution does not contain the appropriate electrolyte balance for longer term maintenance fluid administration.
Inappropriate/excessive use may worsen or create a metabolic acidosis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

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

3.6 Adverse events

None known.

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 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 corticotrophins to prevent high blood pressure and excessive fluid retention during administration of large volumes.
Concomitant administration of colloids requires a dose reduction.

3.9 Administration routes and dosage

Intravenous use.
The volume and rate of infusion will depend upon the clinical condition, existing deficits of the animal, maintenance needs and continuing losses.
Generally, aim to correct hypovolaemia by 50 % initially (ideally over 6 hours but faster if necessary) and reassess by clinical examination.
Deficits are generally in the range of 50 ml/kg (mild) to 150 ml/kg (severe). An infusion rate of 15 ml/kg/hour is recommended in the absence of shock (range 5-75 ml/kg/hour).
In shock, high initial infusion rates, up to 90 ml/kg/hour, are needed. High infusion rates should not be continued for longer than 1 hour unless urine output is restored. The maximum infusion rate should be decreased in the presence of cardiac, renal and pulmonary disease.

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, treatment should involve administering diuretics and stopping the infusion.
Overdose may lead to hypernatraemia, hyperchloraemia, hypokalaemia, cardiac decompensation, hyperhydration and metabolic acidosis.
Clinical signs of excessive overdose include restlessness, hypersalivation, shivering, tachycardia, serous nasal discharge, tachypnoea, moist lung sounds, coughing, protrusion of the eye from the orbit, widespread oedema, vomiting and diarrhoea.
Long-term infusion may cause electrolyte imbalance. Saline solution is not balanced, and it may cause acidaemia because it will increase renal elimination of bicarbonate. Prolonged use may cause hypokalaemia.

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

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.
Sodium is the major cation of the extracellular space and regulates the size of this space together with other anions.
The sodium content and the fluid homeostasis of the body are closely related. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.
An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolarity.
A 0.9 per cent sodium chloride solution has the same osmolarity as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space.

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.
Sodium and chloride are normal components of the body and their balance is maintained by the kidneys. The sodium level of the veterinary medicinal product is similar to the physiological level in the serum.
The kidneys are the major regulator of the sodium and water balance. In cooperation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone), the kidneys are primarily responsible for the maintenance of a constant volume of the extracellular space and regulation of its fluid composition.
Chloride is exchanged for hydrogen carbonate in the tubule system. Thus, it is involved in the regulation of the acid-base balance.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
100 ml: 18 months.
500 ml, 1000 ml and 2000 ml: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Do not store above 25 °C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Polyvinylchloride infusion bag overwrapped with polypropylene.
Pack sizes: Individual fluid bags of 100 ml, 500 ml, 1000 ml and 2000 ml, each supplied with a package leaflet, or boxes containing 40 x 100 ml, 50 x 100 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 12 x 1000 ml, 4 x 2000 ml and 5 x 2000 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

Dechra Regulatory B.V.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA22322/021/001

8. DATE OF FIRST AUTHORISATION

09/08/2013

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

27/05/2026

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).