Animalcare

Aqupharm® 1

9 mg/ml Solution for Injection/Infusion

Statement of the active substance(s) and other ingredient(s)

Each ml contains:
Sodium Chloride 9 mg.
Solution for injection/infusion. Clear, colourless particle free solution.

Indication(s)

Correction of water: sodium imbalances.
Treatment of metabolic alkalosis.
Rehydration in disease conditions which result in excessive loss of water and sodium chloride, and during and after surgery.
A vehicle solution for the administration of other compatible drugs.

Contraindication(s)

Do not use in animals with:
- sodium and water retention including heart failure
- hypernatraemia
- hyperchloraemia
- hyperhydration.

Adverse reactions

Not known under normal conditions of use. Where the product is used as a drug carrier, this can lead to other adverse effects.

Target species

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

Dosage for each species, route(s) and method of administration

Slow intravenous injection or infusion, or subcutaneous injection.
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 (mls) = 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 (mls) = 50 ml x Bodyweight (kg).
Maintenance per day for Rabbits (mls) = 75 – 100 ml x Bodyweight (kg)
(e.g. for a 10 kg dog, the daily maintenance fluid requirement is 10 x 50 = 500 ml).
The administration rate should be adjusted to each animal. The objective is to correct the deficit over 12 - 24 hours.
When given subcutaneously, reduced doses are recommended.
For intravenous infusion, the administration rate should be adjusted to each animal. The objective is to correct the deficit over 12 - 24 hours.

Withdrawal period

Meat and offal: zero days. Milk: zero hours.

Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
After first opening, use immediately and dispose of any unused product.
250 ml, 500 ml, 1000 ml, 3000 ml and 5000 ml bags do not require any special storage conditions.
100 ml bags: Store below 25˚C.

Special warning(s)

Special warnings for each target species: None.
Special precautions for use in animals:
Use with caution in animals with cardiac or renal impairment as sodium overload may occur. It should be noted that sodium excretion may be impaired post-surgery/trauma.
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.
A risk of thrombosis with intravenous infusion should be considered.
This product should not be used for longer than is necessary to correct and sustain circulating volume. Inappropriate/excessive use may worsen or create a metabolic acidosis.
Maintain aseptic precautions.
This product does not contain an antimicrobial preservative.
The solution 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.
The volume and infusion rate must be adapted to the clinical status of each animal.
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 exceed maximum dose rate of 90 ml/kg/hour. This solution does not contain the appropriate electrolyte balance for longer term maintenance fluid administration.
Special precautions to be taken by the person administering the veterinary medicinal product to animals: None.
Use during Pregnancy, Lactation or lay:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according 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 corticotrophins to prevent high blood pressure and excessive fluid retention during administration of large volumes.
Concomitant administration of colloids requires a dose reduction.
Overdose (symptoms, emergency procedures, 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 hupernatraemia, 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 acidemia because it will increase renal elimination of bicarbonate. Prolonged use may cause hypokalaemia.
Incompatibilities:
The compatibility of an added drug with the product must be estimated by monitoring for a color change or appearance of a precipitate of insoluble complexes or crystals. Reference should be made to the SPC of the drug being co-administered for incompatibilities information.
Before adding a drug, verify it is soluble and stable in water at the pH of the product.

Special precautions for the disposal of unused product or waste materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved: July 2016

Other information

Polyvinyl chloride (PVC) bag with polyisoprene/polycarbonate ports, overwrapped with polypropylene.
Pack Sizes: Cardboard box containing 50 bags of 100 ml, 30 bags of 250 ml, 20 bags of 500 ml, 10 bags of 1000 ml, 4 bags of 3000 ml, 2 bags of 5000 ml. Not all pack sizes may be marketed.
To be supplied only on a veterinary prescription.
Marketing Authorisation Number: Vm 10347/4038
Manufacturer responsible for batch release: Infomed Fluids SRL, 50 Theodor Pallady blvd., District 3, 032266 Bucharest, Romania
Marketing Authorisation Holder:
Animalcare Ltd, 10 Great North Way, York YO26 6RB, UK