Animalcare

Aqupharm® 11

(Hartmann's) Solution for Infusion

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

Each ml contains:

Active substance:

Sodium chloride	6.00 mg
Potassium chloride	0.40 mg
Calcium chloride (as dihydrate)	0.204 mg
Corresponding to calcium chloride dihydrate	0.27 mg
Sodium S-lactate (as sodium lactate (50% w/v)	3.20 mg
Sodium	131 mmol/litre
Potassium	5 mmol/litre
Calcium	2 mmol/litre
Bicarbonate (as lactate)	29 mmol/litre
Chloride	111 mmol/litre

Solution for Infusion. Clear, colourless particle free solution.

Indication(s)

Treatment of dehydration of extracellular predominance.
Treatment and prevention of perioperative hypovolaemia and haemorrhagic shock.
Treatment of mild metabolic acidosis.

Contraindication(s)

Do not use in animals with:

- congestive heart failure
- hyperkalaemia
- hypercalcemia
- metabolic alkalosis
- hyperhydration
- severe metabolic or lactic acidosis
- hepatic insufficiency
- Addison's disease
- hypernatraemia.

Adverse reactions

The use of the product can cause metabolic alkalosis, in cases of excessive administration or impaired metabolism of lactate. Not known under normal conditions of use. Where the product is used as a drug carrier, this can lead to other adverse effects. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Target species

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

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

Administer by intravenous infusion.

Management of dehydration including patients with mild metabolic acidosis

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 ongoing 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 maintenance requirement, the following equation should be used;
Maintenance for cattle, horses, sheep, goats, pigs, dogs and cats (mls) = 50ml x Bodyweight (kg) per day.
Maintenance of rabbits (mls) = 75-100ml x Bodyweight (kg) per day (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.

Prevention of perioperative hypovolaemia

Administer at a rate of 5 – 10 ml/kg/hr during anaesthesia.

Treatment of hypovolaemic and haemorrhagic shock

Cattle, horses, sheep, goats, pigs, dogs and rabbits; up to 90 ml/kg/hr
Cats; up to 60 ml/kg/hr.
High infusion rates should not be continued for longer than 1 hour.

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 after EXP. The expiry date refers to the last day of that month.
After first opening, use immediately and dispose of any unused product.
This veterinary medicinal does not require any special storage conditions.

Special warning(s)

Special warnings for each target species:

None.

Special precautions for use in animals:

Do not use unless the solution is clear, free from visible particles, and the container is undamaged. A risk of thrombosis with intravenous infusion should be considered.
Maintain aseptic precautions. This product does not contain an antimicrobial preservative. It is intended for single use only and any unused contents should be discarded.
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 prevent hypothermia.
The volume and infusion rate must be adapted to the clinical status of each animal.
Use of this solution requires monitoring of the clinical and physiological status of the animal especially in cases of:

- severe renal impairment,
- cardiac impairment,
- sodium retention with oedema,
- treatments with corticosteroids and their derivatives.

Monitor serum potassium and serum calcium in treated animals, particularly potassium levels in cases at risk of hyperkalaemia, such as during chronic renal failure.
In animals with hepatic impairment, Lactated Ringer's solution may not produce its alkalising action since lactate metabolism may be altered.
Do not inject intramuscularly.

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 accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Interactions linked to calcium. In case of concomitant blood transfusion, Lactated Ringer's solution should not be administered with the blood in the same infusion set due to the risk of clotting. This veterinary medicinal product contains calcium. Do not add drugs to this solution that may bind (chelate) to calcium.

Overdose (symptoms, emergency procedures, antidotes):

In the presence of volume overload signs (e.g. restlessness, moist lung sounds, tachycardia, tachypnoea or coughing), treatment should involve administering diuretics and stopping the infusion.
An excessive infusion of Lactated Ringer's solution may cause metabolic alkalosis due to the presence of lactate ions.

Incompatibilities:

Compatibility with other medications should be checked prior to mixing in order to avoid precipitate formation, turbidity, or a problem with the pH.
Reference should be made to the SPC of the drug being co-administered for incompatibilities information.
This veterinary medicinal product is incompatible with chlortetracycline, amphotericin B, oxytetracycline, methylprednisolone, and sodium lactate or sodium bicarbonate intravenous infusions. Mixtures with additives and other drugs (e.g. oxalate-, phosphate- and carbonate-/hydrogen carbonate-containing ones) may cause incompatibilities.

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 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 10347/4039
Manufacturer responsible for batch release: Infomed Fluids SRL, 50 Theodor Pallady blvd., District 3, 032266 Bucharest, Romania
Marketing Authorisation Holder:
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