Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 11 (Hartmann's) Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.
Clear, colourless particle free solution.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in animals with:
- congestive heart failure,
- hyperkalaemia,
- hypercalcaemia,
- metabolic alkalosis,
- hyperhydration,
- severe metabolic or lactic acidosis,
- hepatic insufficiency,
- Addison's disease.
- hypernatraemia

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) 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 to 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.

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, the product may not produce its alkalising action since lactate metabolism may be altered.

Do not inject intramuscularly.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
None

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interactions

Interactions linked to calcium.
In case of concomitant blood transfusion, the product 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.

4.9 Amounts to be administered and administration route

Administer by intravenous infusion.

<u>Management of dehydration including patients with mild metabolic acidosis</u>
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)Cattle, horses, sheep, goats, pigs, dogs, cats and rabbits

To calculate the ongoing maintenance requirement, the following equation should be used;
Maintenance for Cattle, Horses, Sheep, Goats, Pigs, Dogs and Cats (mls) = 50 ml x Bodyweight (kg) per day

Maintenance of Rabbits (mls) = 75 - 100 ml 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 peri-operative 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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 product may cause metabolic alkalosis due to the presence of lactate ions.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Solutions affecting the electrolyte balance
ATC vet code: QB05BB01.

5.1 Pharmacodynamic properties

Isotonic crystalloid solutions are for vascular filling and electrolyte replacement. They have an ionic composition very close to the extracellular fluid.
Sodium is the major cation of extracellular fluid. It is responsible for maintaining the volume of liquid and extracellular osmolarity.
Potassium is mainly an intracellular cation.
99% of calcium is present in the skeleton.
Chloride is essentially an extracellular anion.
Lactate produces bicarbonate salts (hence its alkalising effect).

5.2 Pharmacokinetic particulars

The solution diffuses into the extracellular space whose volume is increased accordingly.
The lactate ion is rapidly metabolised by the liver where it is converted to pyruvate used in the Krebs cycle with production of bicarbonates.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Major 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.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
After first opening, use immediately and dispose of any unused product.

6.4 Special precautions for storage

This veterinary medicinal does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

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 3000ml
2 bags of 5000ml

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-I
8020 Oostkamp
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA10491/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 December 2016

10 DATE OF REVISION OF THE TEXT

March 2019