SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm No. 11 Solution for Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Sodium Chloride	0.60% w/v
Potassium Chloride	0.04% w/v
Calcium Chloride, dihydrate	0.027% w/v
Sodium Lactate	0.32% w/v
(containing equal proportions of D and L lactate isomers)	

Excipients

Water for Injections	qs to 100%

Ions

Sodium	131.0 mmol/l
Potassium	5.0 mmol/l
Calcium	2.0 mmol/l
Chloride	111.0 mmol/l
Bicarbonate (as lactate)	29.0 mmol/l

3. PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless solution for infusion, free from particulate matter.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle, dogs and cats.

4.2 Indications for use

To expand the extracellular fluid or to restore extracellular electrolytes:

Dogs and Cats
For the treatment of persistent diarrhoea and in pyometra when a profuse vaginal discharge is present. It will combat metabolic acidosis.

Cattle and Horses
For the treatment of hypovolaemia, and dehydration caused by diarrhoea in calves and gastro-intestinal disease in horses. To treat metabolic acidosis in horses and to aid in the treatment of metabolic acidosis in cattle.

4.3 Contra-indications

Sodium overload may occur in cases with myocardial and renal damage. It should also be appreciated that in the period following surgical interference or severe trauma there may be an inability to excrete excessive sodium. Lactate solutions are to be avoided in liver dysfunction cases.

4.4 Special warnings for each target species

All species
In evaluating an animal for possible fluid therapy the state of hydration, electrolyte balance, acid-base balance, renal function and caloric balance should be considered. Evaluation will be based on history, physical examination and laboratory testing.
Although Aqupharm No. 11 provides potassium chloride, this is only enough to maintain the potassium content of extracellular fluid and would be quite inadequate in those cases with severe potassium loss. Under these circumstances oral potassium supplements must be given. Lactate overdose in cases with heart disease may provoke arrhythmias and heart failure.

Cattle
Cattle have very low amounts of D-lactate dehydrogenase resulting in a slower metabolism of the D-isomer of sodium lactate compared to the L-isomer. Since this product contains equal proportions of both isomers, this may result in a slower correction of the acidosis.

4.5 Special precautions for use

i. Special precautions for use in animals

Before use, the bag should be inspected and rejected if the solution is not clear or if the inner container is damaged.
Aqupharm No.11 should be prewarmed to body temperature to prevent hypothermia.
Thrombosis of a chosen vein is always a possibility with intravenous infusion. If infusion is protracted then another vein should be selected after 12-24 hours.
Cattle

Dehydrated adult cattle can also commonly present with a metabolic alkalosis in which case this product would be unsuitable. Consideration of the likely acid:base imbalance is particularly important in these animals with regards to fluid selection.

ii. Special precautions to be taken by the person administrating the medicinal product to animals

No special precautions required

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Hypernatraemia (sodium overload) or an inability to excrete excessive sodium – see Overdose.

4.7 Use during pregnancy and lactation

Whilst there is no information available to suggest that this solution would not be safe for use in pregnancy or lactation, no specific safety studies have been performed and hence close veterinary supervision is recommended when using this product in these animals.

4.8 Interaction with other medicinal products and other forms of interaction

Drugs should not be mixed in infusion containers or through the giving sets unless the components are of known compatibility. The user should refer to the manufacturer's literature for any drug substance which he or she proposes to co-administer, and also to the Appendix of Drug Incompatibilities in the current edition of The Veterinary Formulary.

4.9 Amount(s) to be administered and administration route

Remove outer bag and protective giving set inlet tab. Push cannula fully into giving set. Prime giving set. Perform venepuncture and immediately attach giving set. Adjust infusion rate as required. Delivery is from a closed circuit, it does not need an air inlet.
Giving sets should be changed every 24 hours.
The quantity of fluid and electrolyte for administration will consider existing deficits, maintenance needs and continuing losses.
The existing deficit is that which has been lost prior to examination. This must be estimated by evaluating the patient's history, making a physical

examination and using laboratory aids (Finco, D.T., Fluid Therapy, *Journal American Animal Hospital Association* (1972) 8, 155). Maintenance therapy is to replace normal losses occurring via urine, faeces, respiratory tract and skin. As a general rule, maintenance therapy requires 50 ml/kg bodyweight/day. Continuing losses during a disease period should be estimated whenever possible, i.e., quantity of vomit, diarrhoea or blood loss.
Indwelling intravenous catheters offer significant advantage in intravenous fluid therapy.
The rate of administration should be considered with each individual patient. The aim should be to correct about half of the calculated deficit in the first 1-2 hours in dogs and cats. In larger animals correcting this may require therapy over 4–8 hours to avoid exceeding maximum infusion rates. As a general rule the following formula is the maximum satisfactory rate (less where cardiovascular or pulmonary disease exists).

Maximum rate = Body wt (kg) × 90 = ml fluid per hour

This rate should be slowed after the first hour and considerably slowed if no urine flow is established. Signs of over rapid administration include restlessness, moist lung sounds, tachycardia, tachypnoea, nasal discharge, coughing, vomiting and diarrhoea.

However, the clinical response of the animal should be used to guide fluid therapy. Total volume to be infused and infusion rate should be adjusted according to regular clinical evaluation of the patient by the responsible veterinarian. Neonatal requirements may be higher than that of adult animals.

The above maximum rate of 90ml/Kg/hr was determined in dogs. Fluid rates in calves should not exceed 80ml/Kg/hr. Maximum fluid rates have not been established in adult cattle and horses although rates of 40ml/Kg/hr have been found to be well tolerated.

4.10 Overdose (symptoms, emergency procedures and antitodes)(if necessary)

Fluid volume overload may result in restlessness, coughing, moist respiratory sounds, tachycardia, tachypnoea, nasal discharge, pulmonary oedema and compromised cardio-respiratory function. The signs may be of more sudden onset in neonates and care should be taken to avoid over infusion in this group – this is common to all crystalloids.
Overdose of sodium containing solutions can potentially induce a hypernatraemia particularly in animals with renal disease. Associated signs of hypernatraemia include pronounced thirst, dry mucous membranes, constipation, hyperpyrexia, CNS disturbances, and ultimately

convulsions. A hypernatraemic state is indicated by the following plasma Na^+ concentrations;
Dogs > 155mEq/l
Cats > 162 mEq/l
Cattle > 145mEq/l
Horse > 150mEq/l

Treatment of volume overload and hypernatraemia; injection of a diuretic

4.11 Withdrawal periods

Cattle/horses meat – zero days
Cattle/horses milk – zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Blood substitutes and perfusion solutions, I.V. solutions, Solutions affecting the electrolyte balance.

ATCVet Code: QB05BB01

5.1 Pharmacodynamic properties

This product is an intravenous solution containing 131 millimoles of sodium, 5 millimoles of potassium, 2 millimoles of calcium, 111 millimoles of chloride, and 29 millimoles of bicarbonate (as lactate) per litre. When administered intravenously it will replace depleted water and electrolytes and restore water balance and extracellular electrolytes.
It will restore plasma volume and correct metabolic acidosis in dogs, cats and horses. It will restore plasma volume and aid in the correction of metabolic acidosis in cattle.

5.2 Pharmacokinetic particulars

Pharmacokinetics cannot readily be applied to fluid therapy since most of the infused solution is predominantly water, which on infusion will become incorporated into water rich plasma.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

Adrenaline; Calcium containing solutions; Compound sodium lactate intravenous solution; Magnesium sulphate; Noradrenaline acid tartrate; Pethidine hydrochloride; Ringer's solution; Sodium bicarbonate intravenous solution; Streptomycin sulphate; Tetracyclines; Vitamins B & C.

6.3 Shelf-life

Packaging Format 1
Shelf-life of the veterinary medicinal product as packaged for sale in 500, 1000, 3000 and 5000ml flexible pouches: 2 years.
Shelf life of the 250ml pack size as packaged for sale: 18 months

Packaging Format 2
Shelf-life of the veterinary medicinal product as packaged for sale 3 years

6.4 Special precautions for storage

Do not store above 25ºC.
For single use only; any remaining solution should be discarded.
This product does not contain an antimicrobial preservative.
Do not freeze.

6.5 Nature and contents of immediate packaging

Packaging Format 1
A colourless, flexible polyvinyl chloride (PVC) bag with a blue twist off giving set port and a re-sealable additives port containing 250, 500ml, 1000ml, 3000ml or 5000ml clear solution.
250ml and 5000ml bags overwrapped with polypropylene
500ml, 1000ml and 3000ml bags overwrapped with HDPE

Packaging Format 2
A colourless, flexible polyvinyl chloride (PVC) bag with re-sealable polyisoprene/polycarbonate giving set and additive ports, containing 250ml, 500ml, 1000ml, 3000ml and 5000ml clear colourless solution.
PVC bags are overwrapped with polypropylene.

Pack sizes
Cardboard box containing
30 bags of 250 ml solution for infusion
20 bags of 500 ml solution for infusion
10 bags of 1000 ml solution for infusion
4 bags of 3000ml solution for infusion
2 bags of 5000ml solution for infusion

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Animalcare Ltd
10 Great North Way
York Business Park
Nether Poppleton
York
YO26 6RB

8. MARKETING AUTHORISATION NUMBER

Vm 10347/4009

9. DATE OF FIRST AUTHORISATION

Date: 7 June 1998

10. DATE OF REVISION OF THE TEXT

Date: July 2015

APPROVED T. NASH **15/07/15**