SUMMARY OF PRODUCT CHARATERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 18 Solution for Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Sodium Chloride	0.18% w/v
Glucose Anhydrous (or Glucose Monohydrate 4.4% w/v)	4.0% w/v

Ions

Sodium	30.0 mmol/l
Chloride	30.0 mmol/l

Also contains 150 calories per litre as glucose

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for infusion

A clear, colourless solution free from particulate matter.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and Cats

4.2 Indications for use, specifying the target species

For maintenance therapy after the fluid balance has been restored. It can be used for the treatment of moderate/prolonged dehydration due to water loss, but in severe cases Aqupharm No. 1 (Sodium Chloride Injection BP) should be given before continuing with Aqupharm No. 18.

4.3 Contraindications

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.

4.4 Special warnings for each target 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.
In animals with potassium deficiency it may be necessary to give additional oral potassium supplements.

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.
The solution should be prewarmed to 37ºC 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.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Wash hands after use.

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, lactation or lay

There are no contra-indications to use of this product during pregnancy and lactation.

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. 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.
The clinical response of the animal rather than formulae or equations should be used to guide fluid therapy. The intravenous route of administration is preferred. Indwelling intravenous catheters offer significant advantage in intravenous fluid therapy. Subcutaneous administration may be used for isotonic and non-irritating solutions.
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. 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.

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

Symptoms: Associated signs of hypernatraemia include pronounced thirst, dry mucous membranes, constipation, hyperpyrexia, CNS disturbances, and ultimately convulsions. A plasma Na+ concentration of > 150 mEq/l and a urine specific gravity of > 1.030 indicates a hypernatraemic state.

Treatment of overdosage: Injection of a diuretic.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolytes with carbohydrates

ATC Vet Code: QB 05 BB 02

5.1 Pharmacodynamic properties

This product is an intravenous solution containing 30mmol/l of sodium, 30mmol/l of chloride and 150calories per litre of glucose. When administered intravenously it will provide maintenance fluid needs after fluid balance has been restored.

5.2 Pharmacokinetic properties

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

Ampicillin; Benzylpenicillin sodium; Cloxacillin sodium; Heparin sodium; Noradrenaline acid tartrate; Sulphadiazine sodium; Tetracyclines.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.
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 composition of immediate packaging

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

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

Pack sizes
Cardboard box containing
20 bags of 500 ml solution for infusion
10 bags of 1000 ml solution for infusion

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary 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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER

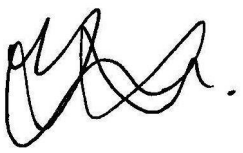
Vm 32742/4021

9. DATE OF FIRST AUTHORISATION

7 June 1993

10. DATE OF REVISION OF THE TEXT

August 2022



Approved: 11 August 2022