PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 1 0.9% w/v Solution for Infusion

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Approx. ion concentration in millimoles per litre: Sodium 150, Chloride 150.

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

Cardboard box containing
50 bags of 100 ml solution for infusion
30 bags of 250 ml solution for infusion
20 bags of 500 ml solution for infusion
10 bags of 1000 ml solution for infusion

5. TARGET SPECIES

6. INDICATION(S)

Sterile non-pyrogenic infusion solution for use in dogs and cats under veterinary supervision

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use. Do not use unless the solution is clear and free from particles.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

This product does not contain an antimicrobial preservative. For single use only. Wash hands after use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Discard any remaining solution.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10347/4006

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 1 0.9% w/v Solution for Infusion

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Presentation

Aqupharm No. 1 is a sterile, preservative free, solution for infusion, presented in a flexible pouch containing:

Sodium Chloride 0.9% w/v

The solution provides sodium 150mmol per litre and chloride 150mmol per litre.

4. INDICATION(S)

Aqupharm No.1 is an isotonic solution used in dogs and cats for the treatment of dehydration to correct water and electrolyte depletion. It is indicated in severe vomiting of acute onset where excessive losses of chloride ions occur and those conditions where the lodgement of foreign bodies interfere with ingestion, i.e. where there is vomiting and/or endotoxic shock.

5. 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.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Aqupharm No. 1 should be prewarmed to 37°C to prevent hypothermia. Remove the 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 50ml/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) x 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.

Once these losses have been replaced, it should be substituted by Aqupharm No.18 to avoid the administration of an excess of sodium ions. Additional oral potassium supplements may be required with protracted use.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Do not freeze. This product does not contain an antimicrobial preservative. Single use only; any remaining solution should be discarded.

12. SPECIAL WARNING(S)

Precautions and warnings:

For animal treatment only. 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.

Aqupharm No.1 is not suitable for protracted use unless there is heavy and continued loss of electrolytes. The difficulty arises from a danger of potassium imbalance. In cases of potassium deficiency the administration of normal saline will increase potassium loss. Where such deficiency is known to occur it may be necessary to give oral potassium supplements.

Treatment of overdosage:

Symptoms:

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

Treatment of overdosage:

Injection of a diuretic.

User warning:

Wash hands after use.

Interaction with other medicines:

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 substances which he or she proposes to co-administer, and also to the Appendix of Drug Incompatibilities in the current edition of The Veterinary Formulary. Aqupharm No.1 is incompatible with Noradrenaline acid tartrate. Do not use this veterinary medical product after the expiry date stated on the label.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM - V

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Package quantities: 100ml, 250ml, 500ml and 1000ml flexible pouches. Not all pack sizes may be marketed.

Pack Sizes: Cardboard box containing 50 bags of 100ml solution for infusion, 30 bags of 250ml solution for infusion, 20 bags of 500ml solution for infusion, 10 bags of 1000ml solution for infusion.

Approved: 03/01/2018