PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm No 11 Solution for Infusion

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sodium Chloride Ph Eur 0.60% w/v
Potassium Chloride Ph Eur 0.04% w/v
Calcium Chloride Dihydrate Ph Eur 0.03% w/v
Sodium Lactate 0.32% w/v

Approx. ion concentration in millimoles per litre: Sodium 131, Potassium 5, Calcium 2, Chloride 111, Bicarbonate (as lactate) 29.

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

5. TARGET SPECIES

6. INDICATION(S)

Sterile non-pyrogenic infusion solution for use in horses, cattle, 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

Cattle and Horses: meat zero days;

Cattle and Horses: milk zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

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]*

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Animalcare Ltd, 10 Great North Way, York, YO26 6RB

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10347/4009

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

Animalcare Ltd, 10 Great North Way, York, YO26 6RB
Manufacturer responsible for batch release: Infomed Fluids SRL,
50 Theodor Pallady blvd., District 3, 032266 Bucharest, Romania

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm No 11 Solution for Infusion

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

Presentation

Aqupharm 11 is a sterile, preservative free, solution for infusion, presented in a flexible pouch, containing:
Sodium Chloride Ph Eur 0.60% w/v
Potassium Chloride Ph Eur 0.04% w/v
Calcium Chloride Dihydrate Ph Eur 0.027% w/v
Sodium Lactate 0.32% w/v (containing equal proportions of D and L lactate isomers)

The approximate ion concentration in millimoles per litre is sodium 131, potassium 5, calcium 2, chloride 111, bicarbonate (as lactate) 29

4. INDICATION(S)

Indications

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.

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.

Lactate solutions are to be avoided in liver dysfunction cases.

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

Dosage and administration

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. 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. 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) 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.

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Cattle and horses: meat zero days

Cattle and horses: milk zero hours

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Do not freeze. This product does not contain an antimicrobial preservative.

For single use only; any remaining solution should be discarded.

12. SPECIAL WARNING(S)

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. 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. It should be noted that 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 amounts of both isomers, this may result in a slower correction of acidosis in this species.

Treatment of overdosage:

Symptoms: Fluid volume overload may result in restlessness, coughing, moist respiratory sounds, tachycardia, 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 as is the case with all crystalloid solutions. Overdose of sodium containing solutions can potentially induce a hypernatraemia particularly in animals with renal disease. Associated signs

of hypenatraemia include pronounced thirst, dry mucous membranes, constipation, hyperpyrexia, CNS disturbances and ultimately convulsions. A hypernatraemic state is confirmed by plasma sodium levels above the reference range for the species.

Treatment of overdosage: Injection of a diuretic.

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.

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

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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 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.

Do not use this veterinary medical product after the expiry date stated on the label.

To be supplied only on veterinary prescription.

Package quantities: 250ml, 500ml, 1000ml, 3000ml and 5000ml.

Pack Sizes: Cardboard box containing 30 bags of 250ml solution for infusion, 20 bags of 500ml solution for infusion, 10 bags of 1000ml solution for infusion, 4 bags of 3000ml solution for infusion, 2 bags of 5000ml solution for infusion. Not all pack sizes may be marketed.

Approved: 03/01/2018