ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 1 (9 mg/ml) solution for injection/infusion

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Sodium Chloride 9 mg

3. PHARMACEUTICAL FORM

Solution for injection/infusion

4. PACKAGE SIZE

50 x 100ml
30 x 250ml
20 x 500ml
10 x 1000ml
4 x 3000ml
2 x 5000ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Slow intravenous injection or infusion or subcutaneous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: zero days.
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: DD/MM/YY

After first opening, use immediately and dispose of any unused product.

11. SPECIAL STORAGE CONDITIONS

100ml bags:
Store below 25 ºC.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4019

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Labels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 1 (9 mg/ml) solution for injection/infusion

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Sodium Chloride 9 mg

3. PHARMACEUTICAL FORM

Solution for injection/infusion

4. PACKAGE SIZE

100ml
250ml
500ml
1000ml
3000ml
5000ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IV, SC
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: zero days.
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: DD/MM/YY

After first opening, use immediately and dispose of any unused product.

11. SPECIAL STORAGE CONDITIONS

100ml bags
Store below 25 ºC.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4019

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Aqupharm 1 (9 mg/ml) solution for injection/infusion

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

Marketing authorisation holder:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:
Laboratoire Bioluz
Zone Industrielle De Jalday
214 Chem. de la Ferme
64500 Saint Jean De Luz
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 1 (9mg/ml) solution for injection/infusion

Sodium Chloride

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

Each ml contains:

Sodium Chloride 9 mg

Solution for injection/infusion. Clear, colourless particle free solution.

4. INDICATION(S)

Correction of water: sodium imbalances.
Treatment of metabolic alkalosis.
Rehydration in disease conditions which result in excessive loss of water and sodium chloride, and during and after surgery.
Vehicle solution for the administration of other compatible drugs.

5. CONTRAINDICATIONS

Do not use in cases of:

- sodium and water retention (due to cardiac, hepatic or renal failure, or enteropathy)
- hypernatraemia

- hyperchloraemia
- hyperhydration.

6. ADVERSE REACTIONS

Not known under normal conditions of use.

Where the product is used as a drug carrier, this can lead to other adverse events.

7. TARGET SPECIES

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

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

Slow intravenous injection or infusion, or subcutaneous injection

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 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 = 500ml)

To calculate the ongoing crystalloid maintenance requirement, the following equation should be used;

Maintenance per day for Cattle, Horses, Sheep, Goats, Pigs, Dogs and Cats (mls) = 50ml x Bodyweight (kg)

Maintenance per day for Rabbits (mls) = 75-100ml x Bodyweight (kg)

(e.g. for a 10 kg dog, the daily maintenance fluid requirement is 10 x 50 = 500ml)

The administration rate should be adjusted to each animal. The objective is to correct the deficit over 12 – 24 hours.

When given subcutaneously, reduced doses are recommended.

For intravenous infusion, the administration rate should be adjusted to each animal. The objective is to correct the deficit over 12-24 hours.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
After first opening, use immediately and dispose of any unused product.
250 ml, 500 ml, 1000 ml, 3000 ml and 5000 ml bags do not require any special storage conditions.

100ml bags: Store below 25 ºC.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

Maintain aseptic precautions.
Use with caution in animals with cardiac or renal impairment as sodium overload may occur. It should be noted that sodium excretion may be impaired post-surgery/trauma.

Use with caution in animals with hypokalaemia. Serum electrolyte levels, water and acid-base balance and the clinical condition of the animal should be closely monitored during the treatment in order to prevent overdose, particularly in cases or renal or metabolic changes.

A risk of thrombosis with intravenous infusion should be considered.

This product should not be used for longer than is necessary to correct and sustain circulating volume. Inappropriate/excessive use may worsen or create a metabolic acidosis.

This product does not contain an antimicrobial preservative.

The solution should be warmed to approximately 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.
Ensure that the solution is clear and contains no visible particles and the unit is perfectly intact. Otherwise, do not use the solution. Discard any unused portion.

Do not exceed maximum dose rate of 90ml/kg/hour. This solution does not contain the appropriate electrolyte balance for longer term maintenance fluid administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

None.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

It is recommended to take appropriate precautions in animals receiving corticosteroids or corticotrophins to prevent high blood pressure and excessive fluid retention during administration of large volumes.

Concomitant administration of colloids requires a dose reduction.

Overdose (symptoms, emergency procedures, antidotes):

It is recommended to maintain a serum sodium less than or equal to 130 mEq / l. In the presence of volume overload signs, treatment should involve administering diuretics and stopping the infusion.

Overdose may lead to hypernatraemia, hyperchloraemia, hypokalaemia, cardiac decompensation, hyperhydration and metabolic acidosis.

Clinical signs of excessive overdose include restlessness, hypersalivation, shivering, tachycardia, serous nasal discharge, tachypnoea, moist lung sounds, coughing, protrusion of the eye from the orbit, widespread oedema, vomiting and diarrhoea.

Long-term infusion may cause electrolyte imbalance. Saline solution is not balanced and it may cause acidemia because it will increase renal elimination of bicarbonate. Prolonged use may cause hypokalaemia.

Incompatibilities:

The compatibility of an added drug with the product must be estimated by monitoring for a colour change or appearance of a precipitate of insoluble complexes or crystals. Reference should be made to the SPC of the drug being co-administered for incompatibilities information.

Before adding a drug, verify it is soluble and stable in water at the pH of the product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Polyvinyl chloride (PVC) bag with polyisoprene/polycarbonate/PVC ports, overwrapped with polyolefin/polyamine.

Pack sizes
Cardboard box containing
50 bags of 100 ml
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.

To be supplied only on a veterinary prescription.

Approved 07 August 2023