ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 11 (Hartmann's) Solution for Infusion

Sodium chloride
Potassium chloride
Calcium chloride (as dihydrate)
Sodium S-lactate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Sodium chloride	6.00 mg
Potassium chloride	0.40 mg
Calcium chloride (as dihydrate)	0.204 mg
Sodium S-lactate	3.10 mg

3. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

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

Intravenous infusion.

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 {month/year}

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

11. SPECIAL STORAGE CONDITIONS

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 32742/4020

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Labels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 11 (Hartmann's) Solution for Infusion

Sodium chloride
Potassium chloride
Calcium chloride (as dihydrate)
Sodium S-lactate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Sodium chloride	6.00 mg
Potassium chloride	0.40 mg
Calcium chloride (as dihydrate)	0.204 mg
Sodium **S**-lactate	3.10 mg

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

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

Intravenous infusion.

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 {month/year}

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

11. SPECIAL STORAGE CONDITIONS

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 32742/4020

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Aqupharm 11 (Hartmann's) Solution for 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 11 (Hartmann's) Solution for Infusion

Sodium chloride
Potassium chloride
Calcium chloride (as dihydrate)
Sodium S-lactate

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

Each ml contains:

Active substance:

Sodium chloride	6.00 mg
Potassium chloride	0.40 mg
Calcium chloride (as dihydrate)	0.204 mg
Corresponding to calcium chloride dihydrate	0.27 mg
Sodium S-lactate (as sodium lactate (50% w/v)	3.10 mg

Sodium	130.32 mmol/litre
Potassium	5.36 mmol/litre
Calcium	1.82 mmol/litre
Bicarbonate (as lactate)	27.65 mmol/litre
Chloride	111.68 mmol/litre

Solution for Infusion.
Clear, colourless particle free solution.

4. INDICATION(S)

Treatment of dehydration of extracellular predominance.
Treatment and prevention of perioperative hypovolaemia and haemorrhagic shock.
Treatment of mild metabolic acidosis.

5. CONTRAINDICATIONS

Do not use in cases of:
- congestive heart failure,
- hyperkalaemia,
- hypercalcaemia,
- metabolic alkalosis,
- hyperhydration,
- severe metabolic or lactic acidosis,
- hepatic insufficiency,
- Addison's disease.
- hypernatraemia.

6. ADVERSE REACTIONS

The use of the product can cause metabolic alkalosis, in cases of excessive administration or impaired metabolism of lactate.

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

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, Horses, Sheep, Goats, Pigs, Dogs, Cats and Rabbits

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

Intravenous infusion.

<u>Management of dehydration including patients with mild metabolic acidosis</u>

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 ongoing 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 maintenance requirement, the following equation should be used;

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

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

(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.

Prevention of peri-operative hypovolaemia

Administer at a rate of 5 – 10ml/kg/hr during anaesthesia.

Treatment of hypovolaemic and haemorrhagic shock

Cattle, Horses, Sheep, Goats, Pigs, Dogs Rabbits; up to 90ml/kg/hr

Cats; up to 60ml/kg/hr

High infusion rates should not be continued for longer than 1 hour.

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 after EXP. The expiry date refers to the last day of that month.
After first opening, use immediately and dispose of any unused product.
This veterinary medicinal does not require any special storage conditions.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

Maintain aseptic precautions.
Do not use unless the solution is clear, free from visible particles, and the container is undamaged. A risk of thrombosis with intravenous infusion should be considered. This product does not contain an antimicrobial preservative. It is intended for single use only and any unused contents should be discarded.

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 prevent hypothermia. The volume and infusion rate must be adapted to the clinical status of each animal.

This veterinary medicinal product should be used 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 of this solution requires monitoring of the clinical and physiological status of the animal especially in cases of:
- severe renal impairment,
-cardiac impairment,
- sodium retention with oedema,
- treatments with corticosteroids and their derivatives.

Monitor serum potassium and serum calcium in treated animals, particularly potassium levels in cases at risk of hyperkalaemia, such as during chronic renal failure.

In animals with hepatic impairment, Lactated Ringer's solution may not produce its alkalising action since lactate metabolism may be altered.

Do not inject intramuscularly.

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:

Interactions linked to calcium.
In case of concomitant blood transfusion, Lactated Ringer's solution should not be administered with the blood in the same infusion set due to the risk of clotting. This veterinary medicinal product contains calcium. Do not add drugs to this solution that may bind (chelate) to calcium.

Overdose (symptoms, emergency procedures, antidotes):

In the presence of volume overload signs (e.g. restlessness, moist lung sounds, tachycardia, tachypnoea or coughing), treatment should involve administering diuretics and stopping the infusion.

An excessive infusion of Lactated Ringer's solution may cause metabolic alkalosis due to the presence of lactate ions.

Incompatibilities:

Compatibility with other medications should be checked prior to mixing in order to avoid precipitate formation, turbidity, or a problem with the pH.

Reference should be made to the SPC of the drug being co-administered for incompatibilities information.

This veterinary medicinal product is incompatible with chlortetracycline, amphotericin B, oxytetracycline, methylprednisolone, and sodium lactate or sodium bicarbonate intravenous infusions. Mixtures with additives and other drugs (e.g. oxalate-, phosphate- and carbonate-/hydrogen carbonate-containing ones) may cause incompatibilities.

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
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 veterinary prescription.

Approved 07 August 2023