[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 11 (Hartmann's) Solution for Infusion (UK(NI), IE)

Aqupharm Ringer-Lactate Solution for Infusion (FI)

Aqupharm Ringer Lactate Solution for Infusion (FR, BE, HU, NL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

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 S-lactate (60 % w/v)	3.10 mg

Electrolyte concentration:

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

Excipients:

Qualitative composition of excipients and other constituents
Water for injections

Clear, colourless particle free solution.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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 to 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.

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, the veterinary medicinal product 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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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

Undetermined frequency (cannot be estimated from the available data):	Alkalosis[1]

[1] In cases of excessive administration or impaired metabolism of lactate.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

Interactions linked to calcium.
In case of concomitant blood transfusion, the veterinary medicinal product 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.

3.9 Administration routes and dosage

Intravenous use (infusion).

Management of dehydration including patients with mild metabolic acidosis

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 = 500 ml)

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

Maintenance for cattle, horses, sheep, goats, pigs, dogs and cats (mls) = 50 ml x Bodyweight (kg) per day

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

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

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 – 10 ml/kg/h during anaesthesia.

Treatment of hypovolaemic and haemorrhagic shock

Cattle, horses, sheep, goats, pigs, dogs, rabbits: up to 90 ml/kg/h

Cats: up to 60 ml/kg/h

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 product may cause metabolic alkalosis due to the presence of lactate ions.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QB05BB01

4.2 Pharmacodynamics

Isotonic crystalloid solutions are for vascular filling and electrolyte replacement. They have an ionic composition very close to the extracellular fluid.
Sodium is the major cation of extracellular fluid. It is responsible for maintaining the volume of liquid and extracellular osmolarity.
Potassium is mainly an intracellular cation.
99% of calcium is present in the skeleton.
Chloride is essentially an extracellular anion.
Lactate produces bicarbonate salts (hence its alkalising effect).

4.3 Pharmacokinetics

The solution diffuses into the extracellular space whose volume is increased accordingly.
The lactate ion is rapidly metabolised by the liver where it is converted to pyruvate used in the Krebs cycle with production of bicarbonates.

5. PHARMACEUTICAL PARTICULARS

5.1 Major 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.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
250 ml: 18 months.
500 ml, 1000 ml, 3000 ml, 5000 ml: 2 years.

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

5.3 Special precautions for storage

250 ml: Store below 25 °C.
500 ml, 1000 ml, 3000 ml, 5000 ml: This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

250 ml, 500 ml, 1000 ml:
Polyvinyl chloride (PVC) bag with 1 polyisoprene/polycarbonate/PVC port and 1 PVC twist-off port, overwrapped with polyolefin/polyamide.

3000 ml, 5000 ml:
Polyvinyl chloride (PVC) bag with 2 polycarbonate/polyisoprene Minitulipe ports, overwrapped with polyolefin/polyamide.

Pack sizes
Cardboard box containing:
30 bags of 250 ml
20 bags of 500 ml
10 bags of 1000 ml
4 bags of 3000 ml
2 bags of 5000 ml

or

Individual bags:
1 bag of 250 ml
1 bag of 500 ml
1 bag of 1000 ml
1 bag of 3000 ml
1 bag of 5000ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

7. MARKETING AUTHORISATION NUMBER(S)

To be filled in nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: to be filled in nationally.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton (if used)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 11 (Hartmann's) Solution for Infusion (UK(NI), IE)

Aqupharm Ringer-Lactate Solution for Infusion (FI)

Aqupharm Ringer Lactate Solution for Infusion (FR, BE, HU, NL)

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. PACKAGE SIZE

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

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use (infusion).

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately and dispose of any unused product.

9. SPECIAL STORAGE PRECAUTIONS

250 ml bags: Store below 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar
An Animalcare Company

14. MARKETING AUTHORISATION NUMBERS

To be filled in nationally.

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Labels (if packed in a carton box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 11 (Hartmann's) Solution for Infusion (UK(NI), IE)

Aqupharm Ringer-Lactate Solution for Infusion (FI)

Aqupharm Ringer Lactate Solution for Infusion (FR, BE, HU, NL)

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. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Intravenous use (infusion).
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately and dispose of any unused product.

7. SPECIAL STORAGE PRECAUTIONS

250 ml bags: Store below 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Labels (for individual bags)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 11 (Hartmann's) Solution for Infusion (UK(NI), IE)

Aqupharm Ringer-Lactate Solution for Infusion (FI)

Aqupharm Ringer Lactate Solution for Infusion (FR, BE, HU, NL)

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. PACKAGE SIZE

250 ml
500 ml
1000 ml
3000 ml
5000 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use (infusion).

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately and dispose of any unused product.

9. SPECIAL STORAGE PRECAUTIONS

250 ml bags: Store below 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar
An Animalcare Company

14. MARKETING AUTHORISATION NUMBERS

To be filled in nationally.

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET (paper leaflet – when cartons are used or concertina label – for individual bags)

1. Name of the veterinary medicinal product

Aqupharm 11 (Hartmann's) Solution for Infusion (UK(NI), IE)

Aqupharm Ringer-Lactate Solution for Infusion (FI)

Aqupharm Ringer Lactate Solution for Infusion (FR, BE, HU, NL)

2. Composition

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 S-lactate (60 % w/v)	3.10 mg

Electrolyte concentration:

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

Clear, colourless particle free solution.

3. Target species

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

4. Indications for use

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. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

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 veterinary medicinal 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 ºC 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.

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:

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.

Major 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.

7. Adverse events

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

Undetermined frequency (cannot be estimated from the available data):	Alkalosis[1]

[1] In cases of excessive administration or impaired metabolism of lactate.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intravenous use (infusion).

Management of dehydration including patients with mild metabolic acidosis

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 = 500 ml)

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

Maintenance for cattle, horses, sheep, goats, pigs, dogs and cats (mls) = 50 ml x Bodyweight (kg) per day

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

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

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 – 10 ml/kg/h during anaesthesia.

Treatment of hypovolaemic and haemorrhagic shock

Cattle, horses, sheep, goats, pigs, dogs, rabbits: up to 90 ml/kg/h

Cats: up to 60 ml/kg/h

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

9. Advice on correct administration

10. Withdrawal periods

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 or 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.
250 ml: Store below 25 °C.
500 ml, 1000 ml, 3000 ml, 5000 ml: This veterinary medicinal product does not require any special storage conditions.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be filled in nationally.

250 ml, 500 ml, 1000 ml:
Polyvinyl chloride (PVC) bag with 1 polyisoprene/polycarbonate/PVC port and 1 PVC twist-off port, overwrapped with polyolefin/polyamide.

3000 ml, 5000 ml:
Polyvinyl chloride (PVC) bag with 2 polycarbonate/polyisoprene Minitulipe ports, overwrapped with polyolefin/polyamide.

Pack sizes
Cardboard box containing
30 bags of 250 ml
20 bags of 500 ml
10 bags of 1000 ml
4 bags of 3000 ml
2 bags of 5000 ml

or

Individual bags:
1 bag of 250 ml
1 bag of 500 ml
1 bag of 1000 ml
1 bag of 3000 ml
1 bag of 5000 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

Local representatives and contact details to report suspected adverse events:
To be filled in nationally.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.