PARTICULARS TO APPEAR ON THE OUTER PACKAGE Carton (if used)

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. PACKAGE SIZE

50 x 100 ml
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 (slow injection or infusion) or subcutaneous use (injection).

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

100 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

Vm 32742/4019

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Sodium Chloride 9 mg

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Intravenous use (slow injection or infusion) or subcutaneous use (injection).
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

100 ml bags: Store below 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar
An Animalcare Company

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE Labels (for individual bags)

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. PACKAGE SIZE

100 ml
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 (slow injection or infusion) or subcutaneous use (injection).

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

100 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

Vm 32742/4019

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

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

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Sodium Chloride 9 mg

Electrolyte concentration:
Sodium 150 mmol/litre
Chloride 150 mmol/litre

Clear, colourless particle free solution.

3. Target species

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

4. Indications for use

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. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

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 veterinary medicinal 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 veterinary medicinal product does not contain an antimicrobial preservative.

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.
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 90 ml/kg/hour. This solution does not contain the appropriate electrolyte balance for longer term maintenance fluid administration.

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:

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.

Major 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.

7. Adverse events

None.

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Intravenous use (slow injection or infusion) or subcutaneous use (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 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.

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 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, 500 ml, 1000 ml, 3000 ml and 5000 ml: This veterinary medicinal product does not require any special storage conditions.

100 ml: Store below 25 ºC.

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

Vm 32742/4019

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

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 3000 ml
2 bags of 5000 ml

or

Individual bags:
1 bag of 100 ml
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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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 reactions:
Animalcare Ltd.
Moorside
Monks Cross
York
YO32 9LB, UK
Tel: +44 (0) 330 8189717
E-mail: animalcare@animalcare.co.uk

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

17. Other information

POM-V

Gavin Hall

Approved: 22 July 2026