[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aqupharm 1 (9 mg/ml) solution for injection/infusion (UK(NI), IE)

Aqupharm Sodium Chloride 9 mg/ml solution for injection/infusion (FR, BE, HU, NL)

Aqupharm Natriumklorid 9 mg/ml solution for injection/infusion (FI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Sodium Chloride 9 mg

The solution provides
Sodium: 150 mmol/litre
Chloride: 150 mmol/litre

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

Do not use in cases of:

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 of 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.

4.6 Adverse reactions (frequency and seriousness)

Not known under normal conditions of use.

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

4.7 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.

4.8 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.

4.9 Amounts to be administered and administration route

Slow intravenous injection or infusion, or subcutaneous injection.

When given subcutaneously, reduced doses are recommended.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 acidaemia because it will increase renal elimination of bicarbonate. Prolonged use may cause hypokalaemia

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolytes.
ATC vet code: QB05BB01.

5.1 Pharmacodynamic properties

Sodium chloride and water are normal constituents of the plasma of animals.

Sodium is the major cation of the extracellular space and regulates the size of this space together with other anions.

The sodium content and the fluid homeostasis of the body are closely related. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.
An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolarity.
A 0.9 per cent sodium chloride solution has the same osmolarity as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space.

5.2 Pharmacokinetic particulars

Sodium chloride administered by the intravenous route quickly joins the normal distribution and metabolism of sodium chloride and water, in the intracellular and extracellular spaces.

Sodium and chloride are normal components of the body and their balance is maintained by the kidneys. The sodium level of the veterinary medicinal product is similar to the physiological level in the serum.
The kidneys are the major regulator of the sodium and water balance. In cooperation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone), the kidneys are primarily responsible for the maintenance of a constant volume of the extracellular space and regulation of its fluid composition.
Chloride is exchanged for hydrogen carbonate in the tubule system. Thus, it is involved in the regulation of the acid-base balance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

6.2 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.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
100 ml, 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.

6.4. Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

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 3000 ml
2 bags of 5000 ml

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.