ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

This information is printed onto the label which is stuck onto the box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion
Sodium chloride

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance:
Sodium chloride 72 mg

Free from bacterial endotoxins.

3. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

20 x 500 ml, 4 x 3000 ml, 2 x 5000 ml.
Individual units of this product may be supplied but each must be accompanied by a package leaflet.

5. TARGET SPECIES

Target species: Cattle, calves, horses, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods: Meat and offal: Zero days;
Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Do not use unless the solution is clear, free from visible particles and the container is undamaged.

10. EXPIRY DATE

EXP:
For single use only. Discard any unused contents.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not freeze.

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

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4091

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

FLUID BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion

Sodium chloride

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance:
Sodium chloride 72 mg

3. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

500 ml, 3000 ml, 5000 ml

5. TARGET SPECIES

Target species: Cattle, calves, horses, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Read the package leaflet before use.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Do not use unless the solution is clear, free from visible particles and the container is undamaged.

10. EXPIRY DATE

EXP:
For single use only. Discard any unused contents.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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

Read the package leaflet before use.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4091

17. MANUFACTURER'S BATCH NUMBER

Lot/EXP: See back of bag.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Hypertonic 72 mg/ml 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:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturer responsible for batch release:
SC Infomed Fluids SRL
50 Theodor Pallady Blvd
District 3
032266 Bucharest
Romania

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion
Sodium chloride

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

1 ml contains:
Active substance:
Sodium chloride 72 mg

Approximate ionic content in millimoles per litre:
Sodium 1232 mmol/litre
Chloride 1232 mmol/litre

Solution for infusion. Clear, colourless solution.

4. INDICATIONS

In all target species: As adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic).

5. CONTRAINDICATIONS

Do not use in animals with:
- Hypertonic hyperhydration (characterised by oedema);

- Renal insufficiency;
- Severe electrolyte disturbances;
- Uncontrolled haemorrhage;
- Pulmonary oedema;
- Retention of water and sodium chloride;
- Cardiac insufficiency;
- Hypertension;
- Hypertonic dehydration (characterised by thirst).

6. ADVERSE REACTIONS

An excess of sodium may cause hypokalaemia, which may be aggravated by the existence of continued loss of potassium and hyperchloraemia.
Erroneous administration of sodium to dehydrated animals may increase the existing extracellular hypertonia, with aggravation of existing disorders, and may cause death.
Rapid infusion may cause oedema, principally pulmonary oedema, especially in cases of concurrent cardiac or renal insufficiency. After rapid administration, hypotension, arrhythmias, haemolysis, haemoglobinuria, bronchoconstriction as well as hyperventilation may occur.
Administration into small peripheral veins may cause signs of pain.
Infusion of hypertonic sodium chloride may provoke diuresis with formation of hypertonic urine.
A risk of thrombosis should be considered.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, calves, horses, dogs and cats.

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

Intravenous use.
The infusion should ideally be warmed to approximately 37°C prior to administration.
Recommended doses are in the range 4-8 ml/kg, and an infusion rate of 1 ml/kg/minute should not be exceeded.
The veterinary medicinal product should be used in conjunction with conventional fluid therapy. The administration of the product is usually followed by the intravenous administration of an isotonic intravenous fluid (e.g. an intravenous 0.9% sodium chloride solution).
Adequate access to drinking water should also be provided.

9. ADVICE ON CORRECT ADMINISTRATION

Warm the pack to approximately 37°C.
Remove the pack from the protective overwrap by tearing downwards from the serrated edge.
Remove the port plug protecting the sterile giving port.
Insert the administration set fully to produce a leak-proof connection and suspend the bag from an infusion stand.
An air inlet is not required.

Prime and regulate the administration set in accordance with the manufacturer's instructions. If the administration set becomes blocked, do not pump solution back into the pack, replace equipment.

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 store above 25°C.
Do not freeze.
This veterinary medicinal product does not contain an antimicrobial preservative. It is intended for single use only and unused contents should be discarded.
Do not use this veterinary medicinal product after the expiry date which is stated on the bag and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:
Excessive administration of chloride may, due to the electrolytes' interaction with the body's bicarbonate buffer system exert an acidifying effect. Therefore, in clinical instances accompanied by acidosis and hyperchloraemia, special care has to be taken if this veterinary medicinal product is to be infused.
Sodium chloride administration may aggravate a pre-existing hypokalaemia.
Adequate access to drinking water should be provided when using the product.
Animals treated with this veterinary medicinal product should be closely observed for possible deterioration of the clinical condition as a consequence of treatment.

Special precautions for use in animals:
Do not use unless the solution is clear, free from visible particles and the container is undamaged.
Maintain aseptic precautions.
Administration of the solution must be accompanied by the opportunity for the animals to drink *ad libitum*.
This veterinary medicinal product should ideally 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.
Any existing haemorrhage should be stopped or controlled before treatment.
Hypertonic solutions must be administered solely by the intravenous route.
Repeated infusion should only be performed after checking sodium concentration and acid-base status.
Rapid infusion of hypertonic NaCl can lead to myelinolysis in the brain in animals with chronic hyponatraemia.
Do not use this product as a vehicle for the administration of other veterinary medicinal products.

Care should be taken to avoid the use of excessive doses (>8 ml/kg) and excessive dose rates (>1 ml/kg/minute).

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

Interaction with other medicinal products and other forms of interaction:
Administer with care to animals that have had prolonged treatment with corticosteroids having a mineralcorticoid action.

Overdose (symptoms, emergency procedures, antidotes):
Overdose of hypertonic sodium chloride solution may lead to an increase in the extracellular volume (extracellular hyperhydration).
Hyperhydration is manifest by agitation and hypersalivation;n these cases, it is appropriate to reduce the rate of infusion drastically or to stop the infusion.
Strict observation of the patient is necessary to safeguard the maintenance of correct diuresis and to avoid causing cardiovascular overload and pulmonary or cerebral oedema.
Fluid output, plasma sodium concentration and blood pressure should be monitored. If hypernatraemia is present, it should be corrected slowly, using water orally if possible, or intravenous 0.9% sodium chloride solution, or for less severe hypernatraemia, an intravenous isotonic electrolyte solution with a low sodium chloride concentration.
An increase of serum osmolarity over 350 mOsm/l may produce cerebral dysfunction and coma.
Overdose of the veterinary medicinal product can cause hypernatraemia.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

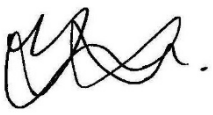
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.
Polyvinylchloride infusion bags overwrapped with polypropylene.
Pack sizes: Individual fluid bags of 500 ml, 3000 ml and 5000 ml, each supplied with a package leaflet, or boxes containing 20 x 500 ml, 4 x 3000 ml or 2 x 5000 ml.
Not all pack sizes may be marketed.

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



Approved: 23 March 2022