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 7.2% w/v solution for infusion

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 litre contains:
Active substance:
Sodium chloride 72 g

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

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

20 x 250 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 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

Cattle, calves, horses, dogs and cats.

6. INDICATION(S)

For intravenous infusion as adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic) in cattle, calves, horses, dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: Zero days
Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

This product does not contain an antimicrobial preservative. Do not use unless the solution is clear, free from visible particles and the container is undamaged.
For single use only. Discard any unused content.

10. EXPIRY DATE

EXP:

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

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

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 10434/4056

POM-V

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FLUID BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 7.2% w/v solution for infusion

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 litre contains:
Active substance:
Sodium chloride 72 g

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

3. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

250 ml, 500 ml, 1000 ml, 2000 ml, 3000 ml, 5000 ml

5. TARGET SPECIES

Cattle, calves, horses, dogs and cats.

6. INDICATION(S)

For intravenous infusion as adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic) in cattle, calves, horses, dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: Zero days
Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

This product does not contain an antimicrobial preservative. Do not use unless the solution is clear, free from visible particles and the container is undamaged.

For single use only. Discard any unused content.

10. EXPIRY DATE

EXP:

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

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

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 10434/4056

POM-V

17. MANUFACTURER'S BATCH NUMBER

Lot/EXP: See back of bag.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Hypertonic 7.2% w/v 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:
Terumo BCT Limited
Old Belfast Road
Millbrook
Larne
Co. Antrim
BT40 2SH
Northern Ireland

SC Infomed Fluids SRL
50 Theodor Pallady Blvd
District 3
032266 Bucharest
Romania

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 7.2% w/v solution for infusion
Sodium chloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 litre contains:
Active substance:
Sodium chloride 72 g

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

Solution for infusion.
Clear, colourless solution.

4. INDICATIONS

This product is administered by intravenous infusion as adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic) in cattle, calves, horses, dogs and cats.

5. CONTRAINDICATIONS

Do not administer to hypernatraemic animals.

6. ADVERSE REACTIONS

Excessive doses and/or dose rates can cause hypernatraemia, hypotension, bradycardia, bronchoconstriction and hyperventilation.

Sodium overload may occur particularly in animals with cardiac or renal impairment, and it should be noted that sodium excretion may be impaired post-surgery/trauma. It should be noted that hypernatraemia may occur in animals that are dehydrated.
A risk of thrombosis with intravenous infusion should be considered.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, calves, horses, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intravenous administration.
Recommended doses are in the range 4-8 ml/kg, and an infusion rate of 60 ml/kg/hr should not be exceeded.
Hypertonic saline (7.2% w/v) should be used in conjunction with conventional fluid therapy. The administration of hypotonic saline 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.
Do not use unless the solution is clear, free from visible particles and the container is undamaged.
The product does not contain an antimicrobial preservative. It is intended for single use only and any unused contents should be discarded.

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

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.
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 precautions for use in animals:
Maintain aseptic precautions.

Adequate access to drinking water should be provided when using the product.
Care should be taken to avoid the use of excessive doses (>8 ml/kg) and excessive dose rates (>60 ml/kg/hr).
The product should ideally be warmed to approximately 37°C prior to administration.

Use during pregnancy or lactation:
Use under veterinary supervision.

Overdose (symptoms, emergency procedures, antidotes):
Excessive doses and/or dose rates can cause hypernatraemia, hypotension, bradycardia, bronchoconstriction and hyperventilation.

Incompatibilities:
It is generally recommended that no agents should be added to the solution.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2016

15. OTHER INFORMATION

For animal treatment only.

Vm 10434/4056

POM-V Prescription Only Medicine - Veterinarian

UK authorised veterinary medicinal product.

Polyvinylchloride infusion bag overwrapped with polypropylene.
Pack sizes: 20 x 250 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml, 4 x 3000 ml, 2 x 5000 ml.
Each carton contains a sufficient number of package leaflets so that individual units may be supplied.
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.
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom

Approved: 22/06/2017