ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 11 (Hartmann's) solution for infusion for cattle, horses, dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains: Active substances:

Sodium (S)-lactate	3.20 mg
Sodium chloride	6.00 mg
Potassium chloride	0.40 mg
Calcium chloride dihydrate	0.27 mg

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZES

20 x 250 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 3 x 3000 ml, 4 x 3000 ml, 2 x 5000 ml, 2 x 5000 ml combi.

5. TARGET SPECIES

Cattle, horses, dogs and cats.

6. INDICATION

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

IV. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNINGS, IF NECESSARY

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

For single use only. Discard any unused contents.

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

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

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

16. MARKETING AUTHORISATION NUMBERS

Vm 10434/4080

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FLUID BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 11 (Hartmann's) solution for infusion for cattle, horses, dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substances:

Sodium (S)-lactate	3.20 mg
Sodium chloride	6.00 mg
Potassium chloride	0.40 mg
Calcium chloride dihydrate	0.27 mg

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZES

250 ml, 500 ml, 1000 ml, 3000 ml, 5000 ml, 5000 ml combi.

5. TARGET SPECIES

Cattle, horses, dogs and cats.

6. INDICATION

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

IV. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

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

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 NUMBERS

Vm 10434/4080

17. MANUFACTURER'S BATCH NUMBER

Lot:

Lot/EXP: See back of bag.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

VETIVEX 11 (Hartmann's) solution for infusion for cattle, horses, dogs and cats

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

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

Or

Industria Farmaceutica Galenica Senese S.r.l.
Via Cassia Nord, Km 351,
Monteroni D'Arbia (SI),
53014, Italy[1]

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 11 (Hartmann's) solution for infusion for cattle, horses, dogs and cats

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml contains:
Active substances:

Sodium (S)-lactate	3.20 mg
Sodium chloride	6.00 mg
Potassium chloride	0.40 mg
Calcium chloride dihydrate	0.27 mg

Sodium: 131 mmol/litre, Potassium: 5 mmol/litre, Calcium: 2 mmol/litre, Bicarbonate (as lactate): 29 mmol/litre, Chloride: 111 mmol/litre

Solution for infusion.
Clear, colourless solution.

[1] The printed leaflet will include only the actual batch release site used.

4. INDICATIONS

For the treatment of dehydration and metabolic acidosis in cattle, horses, dogs and cats.
May be used to correct volume depletion (hypovolaemia) resulting from gastrointestinal disease or shock.

5. CONTRAINDICATIONS

Do not use in animals with:
- hyperkalaemia
- hypercalcaemia
- hypernatraemia
- hyperlactataemia
- hyperhydration
- metabolic alkalosis
- oedema (hepatic, renal, or cardiac)
- Addison's disease

6. ADVERSE REACTIONS

Skin reactions (urticarial, eczema, skin lesions) and allergic oedema are very rarely observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animal treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horses, dogs and cats.

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

Intravenous use. The volume and rate of infusion will depend upon the clinical condition, existing deficits of the animal, maintenance needs and continuing losses. Generally aim to correct hypovolaemia by 50 % initially (ideally over 6 hours but faster if necessary) and reassess by clinical examination.
Deficits are generally in the range of 50 ml/kg (mild) to 150 ml/kg (severe). An infusion rate of 15 ml/kg/hour is recommended in the absence of shock (range 5-75 ml/kg/hour).
In shock, high initial infusion rates, up to 90 ml/kg/hour, are needed. High infusion rates should not be continued for longer than 1 hour unless renal function and urine output are restored. The maximum infusion rate should be decreased in the presence of cardiac, renal and pulmonary disease.

9. ADVICE ON CORRECT ADMINISTRATION

Directions for use:
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.

Use of the Combi port (5000 ml Combi):
The Combi port permits two bags to be connected in sequence so volumes greater than 5 litres may be administered during a single infusion. Each Combi port is protected by a snap-off cover. This should be removed from each of two Combi bags. One spike from each end of a double spike connector unit should be pushed firmly through the Combi port rubber septum of each of the bags. Suspend the bags (one higher than the other) from an infusion stand. To insert the administration set into the giving port of the lower bag, continue through section 'Directions for use'.

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 label after EXP.

12. SPECIAL WARNINGS

Special precautions for use in animals:
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.
Maintain aseptic precautions.
The veterinary medicinal product should be warmed to approximately 37°C prior to administration in order to avoid hypothermia.
This veterinary medicinal product does not contain an antimicrobial preservative. It is intended for single use only and any unused contents should be discarded.
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.

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.
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 product may not produce its alkalising action since lactate metabolism may be altered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

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

Interaction with other medicinal products and other forms of interaction:
This veterinary medicinal product is incompatible with methylprednisolone, and sodium lactate or sodium bicarbonate intravenous infusions. It is generally recommended that no agents should be added.
Interactions linked to calcium.
In case of concomitant blood transfusion, the 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.

Overdose (symptoms, emergency procedures, antidotes):
In the presence of volume overload signs (e.g. restlessness, moist lung sounds, tachycardia, tachypnoea, nasal discharge, coughing, vomiting and diarrhoea), 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.

Incompatibilities:
This veterinary medicinal product is incompatible with methylprednisolone, and sodium lactate or sodium bicarbonate intravenous infusions.

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

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.
Polyvinylchloride infusion bag overwrapped with polypropylene.

Pack sizes: Individual fluid bags of 250 ml, 500 ml, 1000 ml, 3000 ml, 5000 ml and 5000 ml Combi, each supplied with a package leaflet, or boxes containing 20 x 250 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 3 x 3000 ml, 4 x 3000 ml, 2 x 5000 ml and 2 x 5000 ml Combi.
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 18 August 2023