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 1 (9 mg/ml) solution for infusion for cattle, horses, dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Sodium chloride 9 mg

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

40 x 100 ml, 50 x 100 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml, 5 x 2000 ml.

5. TARGET SPECIES

Cattle, horses, dogs and cats.

6. INDICATION

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNINGS

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 REACH AND SIGHT 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

Vm 10434/4079

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

FLUID BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 1 (9 mg/ml) solution for infusion for cattle, horses, dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Sodium chloride 9 mg

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

100 ml, 500 ml, 1000 ml, 2000 ml.

5. TARGET SPECIES

Cattle, horses, dogs and cats.

6. INDICATION

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Read the package leaflet before use.

9. SPECIAL WARNINGS

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

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 REACH AND SIGHT 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.

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

16. MARKETING AUTHORISATION NUMBER

Vm 10434/4079

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

VETIVEX 1 (9 mg/ml) solution for infusion for cattle, horses, dogs and cats [UK, IE]
VETIVEX 9 mg/ml solution for infusion for cattle, horses, dogs and cats [BE, FR, NL]
AQUALEC 9 mg/ml solution for infusion for cattle, horses, dogs and cats [DE, DK, SE]

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

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 1 (9 mg/ml) solution for infusion for cattle, horses, dogs and cats [UK]

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains:
Active substance:
Sodium chloride 9 mg
Sodium: 150 mmol/litre
Chloride: 150 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 in cattle, horses, dogs and cats.
To correct hypovolaemia resulting from shock or gastrointestinal disease (especially where metabolic alkalosis is present, e.g. in cases of sustained vomiting or abomasal disorders in cattle).
May be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally.

5. CONTRAINDICATIONS

Do not use in animals with:
- hypernatraemia
- hyperchloraemia
- hyperhydration
- oedema (hepatic, renal, or cardiac)

6. ADVERSE REACTIONS

None known.
If you notice any side effects or you think that the veterinary medicine has not worked, 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 urine output is 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.

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.
Sodium overload may occur in animals with cardiac or renal impairment. It should be noted that sodium excretion may be impaired post-surgery/trauma.
A risk of thrombosis with intravenous infusion should be considered.
Maintain aseptic precautions.
The product 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.
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.
This product should not be used for longer than is necessary to correct and sustain circulating volume. This solution does not contain the appropriate electrolyte balance for longer term maintenance fluid administration.
Inappropriate/excessive use may worsen or create a metabolic acidosis.

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:
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 (symptoms, emergency procedures, antidotes):
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.

Incompatibilities:
None known.

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

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

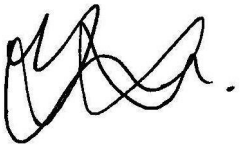
November 2023

15. OTHER INFORMATION

(to be completed nationally)

For animal treatment only. To be supplied only on veterinary prescription.
Polyvinylchloride infusion bags overwrapped with polypropylene.
Pack sizes: Individual fluid bags of 100 ml, 500 ml, 1000 ml and 2000 ml, each supplied with a package leaflet, or boxes containing 40 x 100 ml, 50 x 100 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml and 5 x 2000 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 February 2024