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 for multi packs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 11 (Hartmann's) solution for infusion

2. STATEMENT OF ACTIVE SUBSTANCES

Each 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. PACKAGE SIZE

20 x 250 ml, 30 x 250 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 12 x 1000 ml, 3 x 3000 ml, 4 x 3000 ml, 2 x 5000 ml, 2 x 5000 ml combi.

4. TARGET SPECIES

Cattle, horses, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

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.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/3040
Vm 50406/5045

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL ON FLUID BAG/250 ml, 500 ml, 1000 ml, 3000 ml, 5000 ml, 5000 ml combi.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 11 (Hartmann's) solution for infusion

2. STATEMENT OF ACTIVE SUBSTANCES

Each 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. TARGET SPECIES

Cattle, horses, dogs and cats.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.
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.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 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.

Clear, colourless solution.

3. Target species

Cattle, horses, dogs and cats.

4. Indications for use

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. Special warnings

Special precautions for safe use in the target species:
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 veterinary medicinal product may not produce its alkalising action since lactate metabolism may be altered.

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 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 veterinary medicinal 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:
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 veterinary medicinal product may cause metabolic alkalosis due to the presence of lactate ions.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

Cattle, horses, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Eczema, Skin lesion, Allergic oedema (swelling), Urticaria (hives)

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes 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 periods

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. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 50406/3040
Vm 50406/5045

Polyvinylchloride infusion bags 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, 30 x 250 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 12 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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

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

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

Local representatives and contact details to report suspected adverse reactions:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
SY4 4AS
United Kingdom
Tel: +44 (0)1939 211200

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

17. Other information

Approved 16 June 2026

Gavin Hall