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

Vetivex 3 (Sodium chloride 0.9% w/v and glucose 5% w/v infusion BP)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 litre contains:
Active substances:

Sodium chloride	9 g
Glucose monohydrate	55 g
(equivalent to anhydrous glucose 50 g)	

Approximate ionic content: in millimoles per litre:

Sodium	150 mmol/litre
Chloride	150 mmol/litre

3. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

50 x 100 ml, 20 x 250 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml, 4 x 3000 ml, 2 x 5000 ml

5. TARGET SPECIES

Cattle, calves, horses, dogs and cats.

6. INDICATIONS

This product is administered by intravenous infusion for the treatment of dehydration in cattle, calves, horses, dogs and cats. It may be used to correct hypovolaemia resulting from shock or gastrointestinal disease. It may be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNINGS, 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

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

Vm 10434/4055

POM-V

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FLUID BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetivex 3 (Sodium chloride 0.9% w/v and glucose 5% w/v infusion BP)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 litre contains:
Active substances:

Sodium chloride	9 g
Glucose monohydrate	55 g
(equivalent to anhydrous glucose 50 g)	

Approximate ionic content: in millimoles per litre:

Sodium	150 mmol/litre
Chloride	150 mmol/litre

3. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle, calves, horses, dogs and cats.

6. INDICATIONS

This product is administered by intravenous infusion for the treatment of dehydration in cattle, calves, horses, dogs and cats. It may be used to correct hypovolaemia resulting from shock or gastrointestinal disease. It may be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNINGS, 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

Disposal: Read the 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 10434/4055

POM-V

17. MANUFACTURER'S BATCH NUMBER

Lot:
Lot/EXP: See back of bag

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Vetivex 3 (Sodium chloride 0.9% w/v and glucose 5% w/v infusion BP)

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

Manufacturers 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

Vetivex 3 (Sodium chloride 0.9% w/v and glucose 5% w/v infusion BP)

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 litre contains:
Active substances:

Sodium chloride	9 g
Glucose monohydrate	55 g

(equivalent to anhydrous glucose 50 g)

Approximate ionic content: in millimoles per litre:

Sodium	150 mmol/litre
Chloride	150 mmol/litre

Solution for infusion.
Clear, colourless solution.

4. INDICATIONS

For the treatment of dehydration in cattle, calves, horses, dogs and cats. It may be used to correct hypovolaemia resulting from shock or gastrointestinal disease. It may be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally. The glucose is not a significant calorie source but can provide transient improvement of hypoglycaemia.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

There is a risk of thrombosis with intravenous infusion.

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, ROUTE AND METHOD OF ADMINISTRATION

Administer by intravenous infusion at a rate not exceeding 10 ml/kg/hour.

The product should ideally be warmed to approximately 37°C prior to administration.

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 manufacturers instructions. If the administration set becomes blocked, do not pump solution back into the pack, replace equipment.

10. WITHDRAWAL PERIOD

Zero days.

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.

12. SPECIAL WARNINGS

Special precautions for use in animals:

Infusion rates should not exceed 10 ml/kg/hour to minimise the risk of glycosuria and osmotic diuresis.

Administration of this product to diabetic animals must be conducted with extreme caution.

Sodium overload may occur in animals with cardiac or renal impairment. It should be noted that sodium excretion may be impaired post-surgery/trauma.

Use during pregnancy or lactation:

Use under veterinary supervision.

Overdose (symptoms, emergency procedures, antidotes):

Monitor fluid output. Administration of a diuretic may be necessary.

Incompatibilities:

None known.

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

October 2015

15. OTHER INFORMATION

Vm 10434/4055

Prescription Only Medicine – Veterinarian

UK authorised veterinary medicinal product.
For animal treatment only. To be supplied only on veterinary prescription.
Polyvinylchloride infusion bag overwrapped with polypropylene.
Pack sizes: 50 x 100 ml, 20 x 250 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml, 4 x 3000 ml, 2 x 5000 ml.
Not all pack sizes may be marketed.
Each carton contains a sufficient number of package leaflets so that individual units may be supplied.

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

Approved: 29/06/2017