

## **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 9  
(Ringer's solution for infusion)

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 litre contains:

Active substances:

|                            |        |
|----------------------------|--------|
| Sodium chloride            | 8.60 g |
| Potassium chloride         | 0.30 g |
| Calcium chloride dihydrate | 0.33 g |

Approximate ionic content in millimoles per litre:

|           |                  |
|-----------|------------------|
| Sodium    | 147 mmol/litre   |
| Potassium | 4 mmol/litre     |
| Calcium   | 2.25 mmol/litre  |
| Chloride  | 155.5 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 volume depletion resulting from shock or gastrointestinal disease, especially where hypokalaemia is present (e.g. in cases of sustained vomiting).

### **7. METHOD AND ROUTE OF ADMINISTRATION**

Read the package leaflet before use.

### **8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**9. SPECIAL WARNINGS, 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**

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 10434/4054

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 9  
(Ringer's solution for infusion)

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 litre contains:

Active substances:

|                            |        |
|----------------------------|--------|
| Sodium chloride            | 8.60 g |
| Potassium chloride         | 0.30 g |
| Calcium chloride dihydrate | 0.33 g |

Approximate ionic content in millimoles per litre:

|           |                  |
|-----------|------------------|
| Sodium    | 147 mmol/litre   |
| Potassium | 4 mmol/litre     |
| Calcium   | 2.25 mmol/litre  |
| Chloride  | 155.5 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 volume depletion resulting from shock or gastrointestinal disease, especially where hypokalaemia is present (e.g. in cases of sustained vomiting).

**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**

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**16. MARKETING AUTHORISATION NUMBER**

Vm 10434/4054

POM-V

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

## **B. PACKAGE LEAFLET**



**PACKAGE LEAFLET FOR:**  
Vetivex 9 (Ringer's 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

**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 9  
(Ringer's solution for infusion)

**3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS**

1 litre contains:

Active substances:

|                            |        |
|----------------------------|--------|
| Sodium chloride            | 8.60 g |
| Potassium chloride         | 0.30 g |
| Calcium chloride dihydrate | 0.33 g |

Approximate ionic content in millimoles per litre:

|           |                  |
|-----------|------------------|
| Sodium    | 147 mmol/litre   |
| Potassium | 4 mmol/litre     |
| Calcium   | 2.25 mmol/litre  |
| Chloride  | 155.5 mmol/litre |

Solution for infusion.  
Clear, colourless solution.

#### **4. 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 volume depletion resulting from shock or gastrointestinal disease, especially where hypokalaemia is present (e.g. in cases of sustained vomiting).

#### **5. CONTRAINDICATIONS**

None.

#### **6. ADVERSE REACTIONS**

There is a risk of thrombosis with intravenous infusion.

Excessive infusion rates can cause restlessness, moist lung sounds, tachycardia, tachypnoea, nasal discharge, coughing, vomiting and diarrhoea. 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**

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

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.

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 leakproof 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

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:

This 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.

This product should be used with caution in animals with cardiac or renal impairment as sodium overload may occur.

Maintain aseptic precautions.

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 10434/4054

POM-V

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: 30/06/2017**

