

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **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 18  
Sodium chloride 0.18% w/v and Glucose 4% w/v intravenous solution for infusion BP  
(Vet)

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

1 litre contains:

Active substances:

Sodium chloride	0.18% w/v
Glucose monohydrate	4.4% w/v
(equivalent to anhydrous glucose	4.0% w/v)

Approximate ionic content in millimoles per litre:

Sodium	30 mmol/L
Chloride	30 mmol/L

Each one litre provides approximately 150 kcal.

### **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 and 2 x 5000 ml

Individual units of this product may be supplied but each must be accompanied by a package leaflet.

### **5. TARGET SPECIES**

Cattle, calves, horses, dogs and cats

### **6. INDICATION(S)**

For intravenous infusion for maintenance therapy of dehydration in cattle, calves, horses, dogs and cats. This veterinary medicinal product should be used once the underlying fluid balance has been restored.

### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

### **8. WITHDRAWAL PERIOD**

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

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

The 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**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**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 10434/4058

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 18  
Sodium chloride 0.18% w/v and Glucose 4% w/v intravenous solution for infusion BP  
(Vet)

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

1 litre contains:

Active substances:

Sodium chloride	0.18% w/v
Glucose monohydrate	4.4% w/v
(equivalent to anhydrous glucose	4.0% w/v)

Approximate ionic content in millimoles per litre:

Sodium	30 mmol/L
Chloride	30 mmol/L

Each one litre provides approximately 150 kcal.

**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 and 2 x 5000 ml

Each carton contains sufficient number of package leaflets so that individual units may be supplied.

**5. TARGET SPECIES**

Cattle, calves, horses, dogs and cats

**6. INDICATION(S)**

For intravenous infusion for maintenance therapy of dehydration in cattle, calves, horses, dogs and cats. This veterinary medicinal product should be used once the underlying fluid balance has been restored.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

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

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

The 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**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**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 10434/4058

POM-V

**17. MANUFACTURER'S BATCH NUMBER**

Lot/EXP: See back of bag.



## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:**

Vetivex 18 Sodium chloride 0.18% w/v and Glucose 4% w/v intravenous solution for infusion BP (Vet)

**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:**

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 18  
Sodium chloride 0.18% w/v and Glucose 4% w/v intravenous solution for infusion BP (Vet)

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

1 litre contains:

Active substances:

Sodium chloride	0.18% w/v
Glucose monohydrate	4.4% w/v
(equivalent to anhydrous glucose	4.0% w/v)

Approximate ionic content in millimoles per litre:

Sodium	30 mmol/L
Chloride	30 mmol/L

Each one litre provides approximately 150 kcal.  
Clear, colourless solution for infusion.

#### **4. INDICATIONS**

This product is administered by intravenous infusion for maintenance therapy of dehydration in cattle, calves, horses, dogs and cats. It should be used once the underlying fluid balance has been restored.

#### **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, ROUTES AND METHOD OF ADMINISTRATION**

Intravenous administration.

The volume and rate of infusion will depend upon the clinical condition, existing deficits of the animal, maintenance needs and continuing losses.

Generally, recommended dose for maintenance therapy:

50 ml per kg body weight per day.

The infusion rate should be decreased in the presence of cardiac and pulmonary disease.

The maximum recommended infusion rate is 12 ml/kg/hour, otherwise it is liable to cause glycosuria and osmotic diuresis.

#### **9. ADVICE ON CORRECT ADMINISTRATION**

The solution should ideally be warmed to approximately 37°C prior to administration. Remove the pack from the protective overwrap by tearing downwards from the serrated edge.

Carefully straighten hanger and ports if necessary.

Remove the port plug protecting the sterile giving port. Do this by twisting off the top section while holding the bottom section.

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 bag and carton after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

### Special precautions for use in animals:

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

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

The solution should ideally 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 not be used for prolonged periods of time unless there is continuing excessive loss of electrolytes, as it may provoke hypokalaemia.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

### Use during pregnancy or lactation:

Use under veterinary supervision.

### Overdose (symptoms, emergency procedures, antidotes):

Monitor fluid output and blood glucose. The administration of a diuretic may be necessary.

### Incompatibilities:

Check compatibility of additives prior to administration.

## 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

June 2016

## 15. OTHER INFORMATION

For animal treatment only.  
Vm 10434/4058

POM-V
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 Prescription Only Medicine - Veterinarian

UK authorised veterinary medicinal product.

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

Each carton contains sufficient number of package leaflets so that individual units may be supplied.

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.

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom

**Approved: 29/06/2017**

