

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Lectade Plus Powder for Oral Solution

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<b>Active ingredients</b>	<b>%w/w</b>	<b>g/sachet</b>
<b>Sachet A</b> (Electrolyte mix)		
Sodium chloride	5.933	4.59
Glycine	3.891	3.01
Potassium dihydrogen phosphate	1.758	1.36
Sodium acid citrate	2.327	1.80
Potassium citrate	4.188	3.24
Sodium citrate	0.853	0.66
<b>Sachet B</b>		
Glucose monohydrate	81.037	62.69
<b>Other ingredients</b>		
Erythrosine E127 (Sachet A)	0.007	0.005

When reconstituted as recommended, it contains;

Glycine	20 mmol/L
Sodium	50 mmol/L
Potassium	20 mmol/L
Chloride	39 mmol/L
Citrate	10 mmol/L
Phosphate	5 mmol/L
Glucose	160 mmol/L

### **3. PHARMACEUTICAL FORM**

Powder for oral solution.

Presented in a paired sachet, containing a pink crystalline powder in one, and a white crystalline powder in the other.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Calves

#### **4.2 Indications for use, specifying the target species**

Is indicated as an oral rehydration therapy for the treatment of diarrhoea in calves by reversing the process of dehydration, acidosis and loss of electrolytes associated with diarrhoea, whether caused by bacteria, viruses, cryptosporidia or inappropriate nutrition.

#### **4.3 Contraindications**

None.

#### **4.4 Special warnings for each target species**

None.

#### **4.5 Special precautions for use**

- i. Special precautions for use in animals

None.

- ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

#### **4.6 Adverse reactions (frequency and seriousness)**

None known.

#### **4.7 Use during pregnancy, lactation or lay**

Not applicable.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

The product has been shown to be compatible with oral antibiotics such as amoxicillin, ampicillin and oxytetracycline.

#### **4.9 Amounts to be administered and administration route**

For oral administration only.

The contents of sachets A and B should be added to 2 litres (approximately 3.5 pints) of fresh water, at a temperature of about 35°C.

##### ***Scouring calves***

Immediately scour symptoms show, withdraw milk or milk replacer and offer 2 litres of solution twice daily for two days (four feeds). For the next four feeds offer 1 litre of product solution added to 1 litre of milk or milk replacer. Thereafter feed as normal.

#### *Duration of treatment*

If the scouring is established or severe, thus causing serious dehydration, the solution should be fed three or four times daily. The product may be used on its own for a maximum of four days.

Ensure that adequate colostrums is fed to all calves.

#### *General recommendations*

Keep feeding utensils clean.

Any medicated water which is not consumed within 24 hours should be discarded.

### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

No adverse effects are to be expected from an accidental overdose.

### **4.11 Withdrawal period(s)**

Meat: Zero days.

## **5. PHARMACOLOGICAL PROPERTIES**

A glucose-glycine-electrolyte formulation which is effective in oral rehydration therapy. The underlying principles of this are:

1. Intestinal absorption of glucose and amino acids is an active process linked to the movement of sodium and water.
2. The linked absorption increases net fluid and electrolyte uptake and offsets fluid loss, so reversing the process of dehydration and diarrhoea;
3. When diarrhoea is caused by bacterial enterotoxins, the active transport of glucose and glycine is not impaired;

Diarrhoea may result in dehydration, hyponatraemia, hyperkalaemia and acidosis. Effective oral rehydration therapy will reverse the net secretion of fluid and electrolytes into the gut and promote net absorption of water, electrolytes and nutrients. The active ingredients of the product act in this way. Glucose and glycine are actively absorbed by a sodium-dependent mechanism, bringing about a net uptake of water. In addition, these ingredients also act as a source of energy (glucose) and amino acids (glycine). This increased content of energy and amino acid is particularly important for the calf when milk is withheld during the treatment regime.

Sodium and chloride ions from the salt form an essential part of the sodium-dependent glucose and glycine transport mechanism, which promotes the absorption of water. Potassium dihydrogen phosphate provides potassium, phosphate and hydrogen ions, helping to restore electrolyte balance. Citrate ions further enhance water uptake from the gut and indirectly provide bicarbonate to correct the acidosis of dehydration and diarrhoea. The product has extra citrate ions which aid this process. When made up with water as directed, the product forms an isotonic solution. This is beneficial, as a hypertonic solution would promote further water secretion into the gut, so exacerbating the diarrhoea.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

The full composition of the product is listed under section 2 of this SPC.

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.  
Shelf life after dilution or reconstitution according to direction: 24 hours.

### **6.4 Special precautions for storage**

Store in a dry place.  
Do not store above 25°C.  
Any medicated water which is not consumed within 24 hours should be discarded.

### **6.5 Nature and composition of immediate packaging**

Lectade Plus is presented in twinned laminated sachets of two sizes. The laminate consists of paper (outside), polyethylene, aluminium foil, polyethylene (inside).  
Sachet A contains 14.66g of the electrolyte mix  
Sachet B contains 62.69g of the glucose.  
Available in cartons of 12 or 48 paired sachets.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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

## **7. MARKETING AUTHORISATION HOLDER**

Elanco Europe Ltd  
Form 2, Bartley Way  
Bartley Wood Business Park  
Hook  
RG27 9XA  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

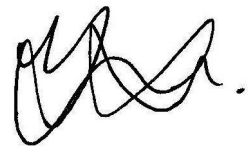
Vm 00879/4177

**9. DATE OF THE FIRST AUTHORISATION**

20 December 1993

**10. DATE OF REVISION OF THE TEXT**

October 2020

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke ending in a dot.

Approved: 01 October 2020