Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

LECTADE Plus Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	% w/w	g/sachet
Sachet A		
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
Sachet B		
Glucose monohydrate	81.037	62.69
Ionic concentration of made up solution		
Sodium	49.8 mM	
Potassium	20.0 mM	
Chloride	39.3 mM	
Citrate	9.5 mM	
Phosphate	5.0 mM	
Glycine	20.0 mM	
Glucose	160.2 mM	
Excipients	% w/w	g/sachet
Erythrosine E127 (Sachet A)	0.007	0.005

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.
Paired sachets containing a pink powder (sachet A) and a white powder (sachet B).

4 CLINICAL PARTICULARS

4.1 Target Species

Calves

4.2 Indications for use, specifying the target species

Lectade Plus 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

In severe cases of dehydration some animals may require additional intravenous re-hydration therapy. In such cases consult a veterinary surgeon.

4.5 Special precautions for use

Special precaution(s) for use in animals
None

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. Lectade Plus has been shown to be compatible with oral antibiotics such as amoxycillin, ampicillin and oxytetracycline.

4.9 Amounts to be administered and administration route

Lectade Plus is 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 Lectade Plus 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. Lectade Plus may be used on its own for a maximum of four days.
Ensure that adequate colostrum 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 expected from an accidental overdose.

4.11 Withdrawal period(s)

Meat : nil

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Lectade Plus is 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 Lectade Plus 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. Lectade Plus has extra citrate ions which aid this process.When made up with water as directed, Lectade Plus 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

Erythrosine (E127)

6.2 Major incompatibilities

None known

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.

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 the electrolyte mix and Sachet B contains the glucose.
Lectade Plus is available in cartons of 12 or 48 paired sachets.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/030/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1996
Date of last renewal: 30th September 2006

10 DATE OF REVISION OF THE TEXT

July 2018