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
Other ingredients		
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

The veterinary medicinal product 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 precautions for use in animals

Not applicable.

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

Not applicable.

Special precautions for the protection of the environment

Not applicable.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Target species: Calves

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for contact details.

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

4.9 Amount(s) 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 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 be expected from an accidental overdose.

4.11 Withdrawal period(s)

Meat and offal: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Oral electrolytes and carbohydrates.

ATCvet code: QA07CQ02

6. PHARMACEUTICAL PARTICULARS

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.

6.1 List of excipients

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

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

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

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

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is presented in twinned laminated sachets of two sizes. The laminate consists of paper (outside), polyethylene, aluminium foil, polyethylene (inside).

Sachet A contains 14.66 g of the electrolyte mix.
Sachet B contains 62.69 g of the glucose.
The veterinary medicinal product is available in cartons of 12 or 48 paired sachets.

Not all pack sizes may be marketed

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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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 FIRST AUTHORISATION

20 December 1993

10. DATE OF REVISION OF THE TEXT

February 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

Approved 15 February 2024