1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lectade Plus Powder for Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Sachet A

Sodium chloride	4.59 g
Glycine	3.01 g
Potassium dihydrogen phosphate	1.36 g
Sodium acid citrate	1.80 g
Potassium citrate	3.24 g
Sodium citrate	0.66 g

Sachet B

Glucose monohydrate	62.69 g

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

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sachet A: Erythrosine (E 127)	 0.005 g

Sachet A: Pink powder
Sachet B: White powder

3. CLINICAL INFORMATION

3.1 Target species

Calves.

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

3.6 Adverse events

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 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 amoxycillin, ampicillin and oxytetracycline.

3.9 Administration routes and dosage

Oral use.

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 the veterinary medicinal 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

The veterinary medicinal product 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 the veterinary medicinal 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 veterinary medicinal product has extra citrate ions which aid this process.When made up with water as directed, the veterinary medicinal product forms an isotonic solution. This is beneficial, as a hypertonic solution would promote further water secretion into the gut, so exacerbating the diarrhoea.

4.1 ATCvet code:

QA07CQ02

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 ºC
Store in a dry place.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/030/001

8. DATE OF FIRST AUTHORISATION

01 October 1996

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

23 October 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).