

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lectade Plus Powder for Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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
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Other ingredient

Sachet A Erythrosine (E 127) 0.005 g

3. TARGET SPECIES

Calves

4. ROUTES OF ADMINISTRATION

Oral Solution.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: Zero Days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

Keep the sachet in the outer carton.

Do not store above 25 °C.

Store in a dry place.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

AVM-GSL

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package
leaflet Carton**

[This template should only be used when all printed information is directly visible on the immediate container and cannot be used if a fold-out or concertina format is proposed.]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lectade Plus Powder for Oral Solution

2. 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
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Excipient

Erythrosine (E 127)	0.005 g
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Sachet A: Pink powder
Sachet B: White powder

3. PACKAGE SIZE

12 paired sachets
48 paired sachets

4. TARGET SPECIES

Calves

5. INDICATIONS FOR USE

Indications for use

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.

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

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

Interactions with other medicinal products and other forms of interaction:

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

Overdose:

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

Major incompatibilities:

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

Keep out of sight and reach of children.

8. ADVERSE REACTIONS

Adverse events

Target species: Calves

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Do not use the veterinary medicinal product if you notice visible signs of damage to the packaging.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: Zero days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C

Store in a dry place

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/4177

Pack sizes

Cardboard box with 12 or 48 paired sachets.

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.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

February 2024

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

PV.GBR@elancoah.com

Manufacturer responsible for batch release:

Elanco France S.A.S, 26 Rue de la Chapelle, 68330 Huningue, France

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after reconstitution according to directions: 24 hours

21. BATCH NUMBER

Lot {number}

22. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

Approved 15 February 2024

