

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON**

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

Lectade Plus Powder for oral solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

**Sachet A**

Glycine	3.01 g
Sodium Chloride	4.59 g
Sodium Citrate	0.66 g
Potassium Citrate	3.24 g
Potassium Dihydrogen Phosphate	1.36 g
Sodium Acid Citrate	1.80 g
Erythrosine (E127) - colourant	0.005 g

**Sachet B**

Glucose Monohydrate	62.69 g
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When reconstituted as recommended, it contains: glycine 20mmol/l, sodium 50mmol/l, potassium 20mmol/l, chloride 39mmol/l, citrate 10mmol/l, phosphate 5mmol/l, glucose 160mmol/l.

**3. PHARMACEUTICAL FORM**

Powder for oral solution

**4. PACKAGE SIZE**

48 paired sachets

**5. TARGET SPECIES**

Calves

<pictogram of calf head>

**6. INDICATION(S)**

Lectade Plus is an oral rehydration therapy that reverses the processes of dehydration, acidosis, and loss of electrolytes associated with diarrhoea in calves, whether caused by bacteria, viruses, cryptosporidia or inappropriate nutrition.

Faster recovery for scouring calves

For rapid rehydration, rapid recovery and rapid correction of acidosis in scouring calves

Treats 8 scouring calves\*

\*at recommended dose rate

## **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Lectade Plus is contained in paired sachets (A & B). It is a palatable, water soluble powder for oral administration only. Always feed sachets A and B together. Dissolve the contents of each paired sachet in 2 Litres (approximately 3.5 pints) of fresh water at a temperature of about 35°C to make a pink solution. Immediately signs of scour are seen, withdraw milk or milk replacer and feed 2 Litres of solution, made up freshly as directed, twice daily for 2 days (4 feeds). For the next 4 feeds, use 1 Litre of Lectade Plus solution mixed with 1 Litre of milk or milk replacer. Thereafter feed as normal. If scouring is established or severe, causing serious dehydration, the 2 Litres of solution should be fed 3 or 4 times daily as necessary to correct the dehydration. Lectade Plus may be used on its own for a maximum of 4 days. Lectade Plus has been shown to be compatible with oral antibiotics such as amoxycillin, ampicillin and oxytetracycline. Keep feeding utensils clean and avoid over feeding. Normal feeding should be resumed after the course of treatment. Adequate colostrum should be fed to calves in the first 12 hours of life. Do not use solution contaminated with foreign material. Discard any unused solution after 24 hours. Do not use in animals that are known to be hypersensitive to the active ingredients. In severe cases of dehydration, some animals may require additional intravenous rehydration therapy. In such cases consult a veterinary surgeon. If signs of disease persist or appear consult the veterinary surgeon.

### **Mixing Instructions**

Prepare a fresh solution before each dose by adding the contents of each paired sachet (A and B) to 2 Litres (approximately 3.5 pints) of fresh water at a temperature of about 35°C. Lectade Plus forms a pink solution to be administered orally.

## **8. WITHDRAWAL PERIOD(S)**

Meat - Zero days.

## **9. SPECIAL WARNING(S), IF NECESSARY**

## **10. EXPIRY DATE**

EXP {month/year}

## **11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of empty sachets in the farm refuse. Used containers should not be recycled.

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

For animal treatment only.  
UK only:

AVM-GSL

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

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBERS**

Vm 00879/4177

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**OTHER INFORMATION**

Manufacturer responsible for batch release:  
Rumenco Limited, Trading as Nettex,  
Eastern Avenue,  
Lichfield,  
Staffordshire WS13 7SE,  
United Kingdom

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

**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 SUBSTANCES**

**Sachet A**

Glycine	3.01 g
Sodium Chloride	4.59 g
Sodium Citrate	0.66 g
Potassium Citrate	3.24 g
Potassium Dihydrogen Phosphate	1.36 g
Sodium Acid Citrate	1.80 g
Erythrosine (E127) - colourant	0.005 g

**Sachet B**

Glucose Monohydrate	62.69 g
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When the contents of each paired sachet (A + B) are dissolved in 2 Litres of water, Lectade Plus forms a pink solution for oral administration.

**3. PHARMACEUTICAL FORM**

Powder for oral solution

**4. PACKAGE SIZE**

**Sachet A**

14.7g Powder for oral solution

**Sachet B**

62.7g Powder for oral solution

**5. TARGET SPECIES**

**Calves**

<pictogram of calf head>

## 6. INDICATION(S)

Faster recovery for scouring calves

For rapid rehydration, rapid recovery and rapid correction of acidosis in scouring calves.

Lectade Plus is isotonic. It contains glucose, the most usable energy source.

Lectade Plus reverses the dehydration, acidosis and loss of electrolytes associated with diarrhoea and actively promotes water and electrolyte uptake.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Sachet A: To be fed only with sachet B

Sachet B: To be fed only with sachet A

### Mixing Instructions

Dissolve the contents of each paired sachet A & B in 2 Litres (approximately 3.5 pints) of fresh water at a temperature of about 35°C, to make a pink solution. Please refer to the carton for full instructions on dosing and administration.

If signs of disease persist or appear consult a veterinary surgeon.

## 8. WITHDRAWAL PERIOD(S)

Meat - Zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

## 10. EXPIRY DATE

EXP {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Store in a dry place.

Do not store above 25°C.

Keep container in outer carton.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Discard any unused solution after 24 hours.

See pack carton for disposal advice.

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

For animal treatment only.

UK only:

AVM-GSL

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

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

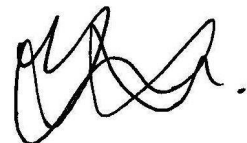
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Lot {number}



Approved: 01 October 2020