

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

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON**

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

Elanco Scour Formula Extra 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
---------------------	---------

This formulation provides both a source of energy and a potent rehydrating action. 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**

Contents: 48 paired sachets

**5. TARGET SPECIES**

Calves

**6. INDICATION(S)**

An oral rehydration therapy for the treatment of calf scour whether caused by viruses, bacteria, cryptosporidia or inappropriate nutrition.

Extra fast recovery for scouring calves  
Treats 8 scouring calves.

Fast recovery  
Fast rehydration

Fast correction of acidosis

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

Elanco Scour Formula Extra is a palatable, water-soluble powder for oral administration only, contained in paired sachets marked A and B. Dissolve the contents of each paired sachet (A + B) into 2 litres of fresh water at a temperature of about 35°C. This forms 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 Elanco Scour Formula Extra 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.

Elanco Scour Formula Extra may be used on its own or with antibiotics.

Always feed sachet A and sachet B together.

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.

Veterinary advice should be sought regarding specific disease control, especially where there is a history of severe disease.

If signs of disease persist or appear, consult a 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 (3.5 pints) of warm water and administer 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.

Keep container in the outer carton.

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

Any medicated water which is not consumed within 24 hours should be discarded. Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers 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.

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

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

**16. MARKETING AUTHORISATION NUMBER**

Vm 00879/4178

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**SACHET**

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

Elanco Scour Formula Extra 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
---------------------	---------

When the contents of each paired sachet, A and B, are dissolved in 2 litres of water, Elanco Scour Formula Extra forms a pink solution.

When reconstituted as recommended, it contains glycine 20mmol/l, sodium 50mmol/l, potassium 20mmol/l, chloride 39mmol/l, phosphate 5mmol/l and glucose 160mmol/l.

**3. PHARMACEUTICAL FORM**

Powder for oral solution

**4. PACKAGE SIZE**

**Sachet A**

Powder for oral solution  
14.7g

**Sachet B**

Powder for oral solution  
62.7g

**5. TARGET SPECIES**

Calves

## 6. INDICATION(S)

Extra fast recovery for scouring calves

Elanco Scour Formula Extra is isotonic.

It provides a source of energy at a concentration that optimises its potent rehydrating action.

Fast recovery

Fast rehydration

Fast correction of acidosis

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

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 Elanco Scour Formula Extra 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 dehydration.

Sachet A: To be fed only with sachet B

Sachet B: To be fed only with sachet A

### Mixing Instructions

Add the contents of each paired sachet (A and B) to 2 litres (3.5 pints) of warm water and administer orally.

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**

Any medicated water which is not consumed within 24 hours should be discarded.

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

For animal treatment 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**

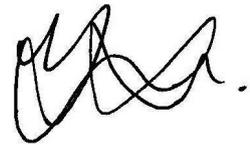
Elanco Europe Ltd  
Form 2, Bartley Way  
Bartley Wood Business Park  
Hook  
RG27 9XA

**16. MARKETING AUTHORISATION NUMBER**

Vm 00879/4178

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}



Approved: 01 October 2020