DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENERGAID powder for oral solution for calves.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

This sachet contains:

Sodium Citrate Dihydrate	5.895% w/w
Sodium Acetate	3.279% w/w
Sodium Propionate	1.157% w/w
Sodium Chloride	2.821% w/w
Potassium Chloride	1.796% w/w
Glucose Anhydrous	81.977% w/w

On reconstitution in 2 litres of water the available ion concentrations are as follows:

Sodium	133 mmol/l
Potassium	20 mmol/l
Chloride	60 mmol/l
Propionate	10 mmol/l
Acetate	33 mmol/l
Citrate	16.54 mmol/l
Dextrose	375 mmol/l

The propionate, acetate and citrate ions together yield 93 mmol/l bicarbonate.

3. PHARMACEUTICAL FORM

Powder for oral solution.
A pink powder

4. PACKAGE SIZE

Net weight not less than: 165 g

5. TARGET SPECIES

Calves

6. INDICATION(S)

ENERGAID is a high calorific content oral rehydration product indicated in the treatment of scour in calves. ENERGAID acts by reversing the processes of dehydration, electrolyte loss, acidosis and weight loss associated with scour in calves. Efficacy has been demonstrated in *E. coli* infected calves.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One sachet provides one dose

ENERGAID is intended for oral administration only. Prepare a fresh solution by mixing the contents of a single sachet with 2 litres of water. This should be administered twice daily for 2 days. For the next 2 days, 1 litre of the solution and 1 litre of milk (either mixed together or fed separately) are administered morning and evening. Thereafter a normal diet is resumed. If symptoms are severe, the solution may be fed 3 or 4 times daily. The solution may be administered on its own for a maximum of 4 days. Normal feeding should be resumed after the course of treatment. A nipple bottle or tube feeder may be used if considered appropriate.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Keep feeding utensils clean and avoid overfeeding. Adequate colostrum should have been fed to calves.
Care should be taken in the correct preparation of the solution, given the high calorific content. Do not use solution contaminated with foreign material.
In severe cases some calves may require additional intravenous therapy. In such cases consult a veterinary surgeon. If signs of disease persist or re-appear the veterinary surgeon or veterinary practitioner should re-evaluate the situation.

A fine deposit of insoluble carrier may remain after dissolving the contents of the sachet, this does not affect the efficacy of the product. Milk or milk replacer may continue to be administered at the onset of Energaid administration, if deemed appropriate by a veterinary surgeon.

For further information please refer to carton

10. EXPIRY DATE

EXP.:

11. SPECIAL STORAGE CONDITIONS

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

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

Discard any unused solution after 24 hours. Dispose of any unused solution in slurry or dirty water.

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 REACH AND SIGHT OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Marketed by:
Elanco Animal Health
Eli Lilly and Company Limited, Basingstoke, Hampshire

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4127
ML: 2000/01

17. MANUFACTURER'S BATCH NUMBER

BN:
D.O.M.:

DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENERGAID powder for oral solution for calves.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition	% w/w
Sodium Citrate Dihydrate	5.895
Sodium Acetate	3.279
Sodium Propionate	1.157
Sodium Chloride	2.821
Potassium Chloride	1.796
Glucose anhydrous	81.977

On reconstitution in 2 litres of water the available concentrations are as follows:

Sodium	133	mmol/l
Potassium	20	mmol/l
Chloride	60	mmol/l
Propionate	10	mmol/l
Acetate	33	mmol/l
Citrate	16.54	mmol/l
Glucose	375	mmol/l

The propionate, acetate and citrate ions together yield 93 mmol/l bicarbonate.

3. PHARMACEUTICAL FORM

Powder for oral solution.
A pink powder

4. PACKAGE SIZE

165 g sachet

ENERGAID is available in cartons of 24 sachets. One sachet is made up in 2 litres of water.

5. TARGET SPECIES

Calves

6. INDICATION(S)

ENERGAID is a high calorific content oral rehydration product indicated in the treatment of scour in calves. Energaid acts by reversing the processes of dehydration, electrolyte loss, acidosis and weight loss associated with scour in calves. Efficacy has been demonstrated in *E. coli* infected calves.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: A solution for oral administration is prepared as follows: dissolve the contents of one sachet in 2 litres of clean warm water.

Administration: Two litres of the solution, prepared as directed, is given twice daily for 2 days. For the next 2 days, 1 litre of solution and 1 litre of milk (either mixed together or fed separately) are administered morning and evening. Thereafter, a normal diet is resumed. If symptoms are severe, the solution may be fed 3 or 4 times daily. The solution may be given for a maximum of 4 days only, when administered on its own. Normal feeding should be resumed after the course of treatment. A nipple bottle or tube feeder may be used if considered appropriate.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Keep feeding utensils clean and avoid overfeeding.
Adequate colostrum should have been fed to calves.
Care should be taken in the correct preparation of the solution, given the high calorific content.
Milk or milk replacer may continue to be administered at the onset of Energaid administration, if deemed appropriate by a veterinary surgeon.
Do not use solution contaminated with foreign material.
In severe cases some calves may require additional intravenous therapy. In such cases consult a veterinary surgeon. If signs of disease persist or re-appear the veterinary surgeon or veterinary practitioner should re-evaluate the situation.

Overdose:
The product has been demonstrated to be well tolerated in the target species. Given the osmotic character of the product, overdose may lead in some cases to softening of the faeces. Therefore, care should be taken in the correct preparation of the resulting oral rehydration solution.

If signs of disease persist or appear consult a veterinarian.

Interaction with other medicinal products and other forms of interaction:
Not investigated.

10. EXPIRY DATE

EXP.

11. SPECIAL STORAGE CONDITIONS

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Discard any unused solution after 24 hours. Dispose of any unused solution in slurry or dirty water.

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FURTHER INFORMATION

ENERGAID is best dissolved by slowly adding the contents of one sachet to 2 litres of warm water, stirring gently. A fine deposit of insoluble carrier may remain after dissolving the contents of the sachet, this being of no significance to product efficacy. The solution is formulated to provide both high levels of sodium (133 mmol/l) to optimise water absorption and also to provide bicarbonate precursors for the correction of acidosis. It has been demonstrated (in independent trials) that ENERGAID is able to counter the hypoglycaemia and weight loss normally associated with scour in calves, without interfering with rehydration. Faecal consistency may remain soft for the initial 48 hours post pure ENERGAID administration - this does not affect the rehydration process.

The product provides an adequate source of nutrients and electrolytes to correct the symptoms associated with diarrhoea. In particular, it provides potassium to counteract decreasing intracellular potassium levels.

The intestinal absorption of water is dependant largely on sodium absorption. The concentration of sodium at a level of 133 mmol/l optimises the basic rehydrating ability of the product. Certain compounds including glucose and the bicarbonate precursors, citrate, propionate and acetate are able to assist enteric sodium uptake.

Absorption and metabolism of the bicarbonate precursors provides a potential 93 mmol/l of bicarbonate which has an important role to play in correcting acidosis, and terminally are an additional source of energy for the weakened calf. The final reconstituted solution also provides 375 mmol/l of glucose providing a high calorific content. Glucose, citrate and propionate all enter the Tricarboxylic Acid (Krebs) Cycle leading to the formation of energy, whilst acetate although utilised by a different route still yields energy.