IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10999/064/001**
Case No: 7006734

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Norbrook Laboratories Limited

Station Works, **Newry**, **Co. Down BT35 6JP**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Energaid

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **29/09/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Energaid.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances		
Sodium Citrate	5.895%	w/w
Sodium Acetate Anhydrous	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
Excipients		
Sunset Yellow (E110)	0.06%	w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution.
A water soluble powder that is pink in colour.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves.

4.2 Indications for use, specifying the target species

Energaid is a calorific oral rehydration product indicated for the reversal of the process of dehydration, electrolyte loss, metabolic acidosis and weight loss associated with scour in calves whether due to nutritional, bacterial, viral or protozoal causes.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Avoid over feeding. Keep feeding utensils clean.
Do not use solution contaminated by foreign material.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

Dosage:
A solution, which is administered orally, is prepared as follows: dissolve the contents of one sachet in 2 litres (3 ½ pints) of warm water.

Administration:
All milk and milk replacer is withdrawn on first signs of scour. Two litres of the solution, freshly prepared as directed, is given twice daily for 2 days. The solution provides an adequate source of nutrients and electrolytes which are readily absorbed. For the next 4 feeds (two days), 1 litre of solution and 1 litre of milk replacer is administered. Thereafter normal diet is resumed. If symptoms are severe, the solution may be given for a maximum of 4 days only, when administered on its own.
Discard any unused solution after 24 hours.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal Period(s)

Nil.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QA07CQ
Pharmacotherapeutic Group: Oral rehydration formulations for veterinary use

Energaid is formulated to correct dehydration and acidosis in diarrhoeic calves whilst also providing a source of energy. It also provides potassium, to counteract decreasing intracellular potassium content a common sequel to the diarrhoeic process.

The intestinal absorption of water is dependant largely on sodium absorption. Within reason the more available sodium, the more body fluid that can be replaced. The concentration of sodium at a level of 133 mmol/1 in Energaid optimises the basic rehydrating ability of the product. Certain compounds are able to assist enteric sodium uptake. Glucose and the bicarbonate precursors, citrate, propionate and acetate, assist in the enteric sodium absorption pathway.

The bicarbonate precursors listed above in the concentrations present within a solution of Energaid provides 93 mmol/L of bicarbonate which promote the absorption of sodium and hence water aiding the process of rehydration.

Absorption and metabolism of the bicarbonate precursors provides bicarbonate which has an important role to play in correcting acidosis, in addition to providing a greater stimulus for the uptake of sodium. Energaid also provides 375 mmol/L of glucose, as an energy source.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sunset Yellow (E110)
Colloidal Anhydrous Silica

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Aluminium foil sachets.
Cartons of 24 sachets each containing not less than 165g.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

None.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited,
Station Works,
Camlough Road,
Newry,
Co. Down, BT35 6JP,
Northern Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/64/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14th November 2006

10 DATE OF REVISION OF THE TEXT

29th September 2009