SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketosaid 99.96% w/w Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each ml contains 0.9996 ml of active substance

Qualitative composition	Quantitative composition
Propylene glycol	99.96% w/w
Excipients:	
Carmoisine	0.04% w/w

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution
A red, viscous, non-aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Sheep

4.2 Indications for use, specifying the target species

Ketosaid is used as an aid in the treatment of acetonaemia and ketosis in cattle and sheep.

4.3 Contraindications

For oral administration only.

4.4 Special Warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

As Ketosis in sheep arises from prenatal metabolic stress, treatment with Ketosaid may be continued until symptoms resolve or until parturition. During this time a general improvement in nutritional status is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental eye contact, wash eyes with plenty of clean water. If irritation occurs, seek medical attention. In case of contact with skin, remove any contaminated clothing and wash affected area thoroughly with soap and water. If irritation occurs seek medical advice.
Ingestion: If accidentally swallowed, seek medical advice.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

Ketosaid can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts to be administered and administration route

Cattle: 200 ml twice daily on first day and 100 ml twice daily for next three days, administered orally as a drench.

Sheep: 100 ml daily for four days, administered orally as a drench.

Prior to administration, doses should be measured accurately by decanting Ketosaid from this container into a clear, dry, suitably sized vessel graduated in millilitres (e.g. measuring jug).

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

None

4.11 Withdrawal period

Meat: Zero days
Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Propylene Glycol

ATC Vet Code: QA16QA01

5.1 Pharmacodynamic properties

Propylene glycol is present as an energy source. It is readily absorbed from the rumen and is glycogenic, the intermediate oxidation products being pyruvate and lactate. When administered over a 3- 4 day period propylene glycol is effective in elevating blood glucose levels.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmoisine (E122)

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^{o}C.

6.5 Nature and composition of immediate packaging

A white, opaque, high density polyethylene can, with a white polypropylene cap (screw fit). Contains either; 1, 2.5, 5 and 10 litres.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4072

9. DATE OF FIRST AUTHORISATION

30 June 1986

10. DATE OF REVISION OF THE TEXT

28 August 2008