SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combivit Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Thiamine Hydrochloride	3.50 % w/v
Riboflavin Sodium Phosphate	0.05 % w/v
Pyridoxine Hydrochloride	0.70 % w/v
Nicotinamide	2.30 % w/v
Ascorbic Acid	7.0 % w/v

Excipients:

Chlorocresol (as preservative)	0.1 % w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, pale yellow liquid, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Target species

Horses
Cattle
Sheep

4.2 Indications for use, specifying the target species

For the treatment of cerebrocortical necrosis in cattle and sheep, the treatment of bracken poisoning in horses and for the treatment of Vitamin B deficiencies in horses, cattle and sheep.

4.3 Contra-indications

Anaphylactic reactions, particularly in the horse, may occur following intravenous administration. When this route is used, the product should be given slowly and may be diluted with sterile saline or dextrose saline solution.

4.4 Special Warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None known.

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

Care should be taken to avoid accidental self-injection.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

There may be slight irritation at the injection site when the product is given by the subcutaneous or intramuscular routes.

4.7 Use during pregnancy, lactation or lay

Combivit can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer by subcutaneous, deep intramuscular or slow intravenous injection. The dose should be repeated daily as required. Normal aseptic precautions should be observed.

Horses, Cattle	20 - 30 ml
Calves, Foals	5 - 10 ml
Sheep	5 - 10 ml

If dose volume exceeds 20 ml, it should be divided and injected into two sites.

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

Not applicable.

4.11 Withdrawal period

Meat : Zero days
Milk : Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins

ATC Vet Code: QA11EB

5.1 Pharmacodynamic properties

Thiamine Hydrochloride (Vitamin B_1) acts as a co-enzyme in the breakdown of glucose and glycogen. Riboflavin Sodium Phosphate (Vitamin B2) is phosphorylated to form the co-enzymes Riboflavin-5-phosphate and Flavin Adenine Dinucleotide (FAD) which act as hydrogen recipients and donors.
Pyridoxine Hydrochloride (Vitamin B6) is converted to pyridoxal phosphate which functions as a co-enzyme with the transaminases and decarboxylases in the metabolism of proteins and amino acids. Nicotinamide is converted into the essential co-enzymes Nicotinamide Adenine Dinucleotide (NAD) and Nicotinamide Adenine Dinucleotide Phosphate (NADP).
Vitamin C (Ascorbic Acid) is involved in the conversion of folic acid to tetrahydrofolic acid and the conversion of proline to hydroxyproline which is essential to the formation of collagen.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Disodium Edetate
Propylene Glycol
Sodium Hydroxide
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Protect from light. Do not store above 25°C. Following withdrawal of first dose use within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

Combivit is marketed in 50 ml and 100 ml amber Type II glass vials, sealed with bromobutyl bungs and aluminium caps.
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: 02000/4118

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 21st December 1993

10. DATE OF REVISION OF THE TEXT

October 2008.