Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Combivit Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Thiamine Hydrochloride	35 mg
Riboflavin Sodium Phosphate	0.5 mg
Pyridoxine Hydrochloride	7 mg
Nicotinamide	23 mg
Ascorbic Acid	70 mg

Excipients

Chlorocresol (preservative)	1 mg

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Solution for injection

A clear, pale yellow sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep, Pigs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substances.

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 product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

Combivit may occasionally cause local reaction at the site of injection. This should resolve naturally within a short period of time.

4.7 Use during pregnancy, lactation or lay

Combivit can be safely administered to pregnant and lactating animal.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Administer by subcutaneous or intramuscular injection. The dose should be repeated daily as required. Avoid the introduction of contamination during use

Cattle	20 – 30 ml
Calves	5 – 10 ml
Sheep, Pigs	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(s)

Edible tissues and milk: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Therapeutic Group; Vitamin B complex with Vitamin C.
ATC Code; QA11EB

Thiamine Hydrochloride (Vitamin B1) 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

Disodium Edetate
Propylene Glycol
Chlorocresol
Sodium Hydroxide Solution
Water for Injection

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Once a vial has been broached the contents should be used within 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

50 ml and 100 ml Type II glass vials (amber), sealed with bromobutyl bungs (grey) and aluminium caps.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1991
Date of last renewal: 30 September 2006

10 DATE OF REVISION OF THE TEXT

January 2019