PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combivit Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Thiamine Hydrochloride (Vitamin B_1)	3.50 % w/v
Riboflavine Sodium Phosphate (Vitamin B_2)	0.05 % w/v
Pyridoxine Hydrochloride (Vitamin B_6)	0.70 % w/v
Nicotinamide	2.30 % w/v
Ascorbic Acid (Vitamin C)	7.0 % w/v
Chlorocresol (Preservative)	0.10 % w/v

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

Multidose vials of 50 ml and 100 ml.
Not all pack sizes may be marketed.

5. TARGET SPECIES

Horses, Cattle and Sheep

6. INDICATION(S)

Combivit may be used in the following cases:

1) Wherever deficiency of vitamin B group is suspected in horses, cattle and sheep.
2) In treatment of cerebrocortical necrosis in cattle and sheep.
3) In treatment of bracken poisoning in horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

SPECIES	DOSAGE
Horses, cattle	20 - 30 ml
Calves, foals	5 - 10 ml
Sheep	5 - 10 ml

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

8. WITHDRAWAL PERIOD

Withdrawal period for meat and milk: Zero days/hours.

9. SPECIAL WARNING(S), IF NECESSARY

Anaphylactoid reactions, particularly in the horse may occur following intravenous administration. When this route is used Combivit should be given slowly and may be diluted with sterile saline or sterile dextrose saline solution. This may be achieved by drawing sterile diluting solution into a syringe, followed by the required volume of Combivit. The diluted product must be administered immediately after preparation and must not be stored. Aseptic precautions should be observed. There may be slight irritation at the site of injection when the product is given by the subcutaneous or intramuscular routes.

10. EXPIRY DATE

D.O.M.:
Exp.:

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this carton, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light.
Keep container in outer carton

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

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in the farm refuse. Used containers should not be recycled.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:

1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4118

17. MANUFACTURER'S BATCH NUMBER

B.N.:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combivit Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Thiamine Hydrochloride (Vitamin B_1)	3.50 % w/v
Riboflavine Sodium Phosphate (Vitamin B_2)	0.05 % w/v
Pyridoxine Hydrochloride (Vitamin B_6)	0.70 % w/v
Nicotinamide	2.30 % w/v
Ascorbic Acid (Vitamin C)	7.0 % w/v
Chlorocresol (Preservative)	0.10 % w/v

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml/100 ml

5. TARGET SPECIES

Horses, Cattle and Sheep

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous intramuscular or slow intravenous injection. Dose should be repeated daily, as required.
Normal aseptic precautions should be observed.

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

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

8. WITHDRAWAL PERIOD

Meat/Milk – zero days/hours

9. SPECIAL WARNING(S), IF NECESSARY

Further Information: See Carton

10. EXPIRY DATE

D.O.M.:
Exp.:
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light.
Keep container in outer carton.

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

Rinse containers thoroughly with water. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

FOR ANIMAL TREATMENT ONLY.

POM-VPS
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4118

17. MANUFACTURER'S BATCH NUMBER

B.N.:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

Approved: 21/06/2017