

PARTICULARS TO APPEAR ON THE OUTER CARTON AND IMMEDIATE PACKAGE {Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intravit 12 Solution for Injection, 0.05% w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml containing cyanocobalamin 0.05% w/v and phenol 0.5% w/v (as a preservative)

3. PHARMACEUTICAL FORM

An aqueous solution for injection

4. PACKAGE SIZE

5. TARGET SPECIES

Cattle, horses, sheep, pigs.

6. INDICATION(S)

Carton: Cyanocobalamin (vitamin B12) is essential for the synthesis of nucleic acids. Consequently it plays an essential role in cell metabolism and the maintenance of metabolic functions including haemopoiesis.

Label: Maintenance of metabolic functions especially the synthesis of nucleic acid in cattle, horses, sheep and pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer by intramuscular or subcutaneous injection, once or twice a week:

Normal aseptic precautions should be observed

Cattle, horses	: 2 - 5 ml
Calves, foals	: 1 - 3 ml
Sheep, pigs	: 0.5 - 1.5 ml

Carton ONLY: Ensure that suitable equipment is used when administering small doses.

8. WITHDRAWAL PERIOD

Meat – Zero days Milk – Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

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

Further information: see package leaflet

10. EXPIRY DATE

Label ONLY: Once broached use by ...

11. SPECIAL STORAGE CONDITIONS

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

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

Carton ONLY: Keep container in outer carton

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

Dispose of empty 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]

POM- VPS

For animal treatment only. To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

Station Works

Newry

Co. Down

BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4116

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Norbrook Laboratories Limited

Station Works

Newry

Co. Down

BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intravit 12 Solution for Injection, 0.05% w/v

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

An aqueous solution for injection containing cyanocobalamin 0.05% w/v and phenol 0.5% w/v as a preservative

4. INDICATION(S)

Cyanocobalamin (vitamin B12) is essential for the synthesis of nucleic acids. Consequently it plays an essential role in cell metabolism and the maintenance of metabolic functions including haemopoiesis.

5. CONTRAINDICATIONS

None known

6. ADVERSE REACTIONS

If you notice any serious side effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horses, sheep, pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

By intramuscular or subcutaneous injection, once or twice a week:

Normal aseptic precautions should be observed

Cattle, horses	: 2 - 5 ml
Calves, foals	: 1 - 3 ml
Sheep, pigs	: 0.5 - 1.5 ml

9. ADVICE ON CORRECT ADMINISTRATION

Ensure that suitable equipment is used when administering small doses.

When administering to a large number of animals a multiple dose injector must be used.

10. WITHDRAWAL PERIOD(S)

Meat – Zero days Milk – Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children. Do not store above 25°C. Protect from light. Keep container in outer carton. 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 package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided

12. SPECIAL WARNING(S)

Care should be taken to avoid accidental self-injection or ingestion. In the case of accidental self-injection or ingestion, seek medical advice as a precautionary measure.

Following skin/eye contamination, wash/irrigate area thoroughly with cold water. Seek medical attention if irritation persists.

Wash hands after use.

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of empty containers in the farm refuse. Used containers should not be recycled.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION>

POM – V To be supplied only on veterinary prescription

Vm 02000/4116

Package quantities: multidose vials of 100 ml

Approved: 10/01/2018

A handwritten signature in black ink, appearing to read 'J. Berg'.