

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intravit 12 Solution for Injection, 0.05% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

<u>Qualitative</u>	<u>Quantitative</u>
Cyanocobalamin (Vitamin B ₁₂)	0.05% w/v

Excipients:

Phenol	0.5% w/v
--------	----------

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A sterile, clear, red aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, sheep, pigs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 Special Warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Normal aseptic precautions should be observed.

Ensure that suitable equipment is used when administering small dose volumes.

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

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

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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Intravit 12 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 intramuscular or subcutaneous injection, once or twice a week:

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

Long term supplementation should be reviewed at least annually.

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: Cyanocobalamin

ATC Vet Code: QB03BA01

5.1 Pharmacodynamic properties

Cyanocobalamin (Vitamin B₁₂) is of importance in the utilisation of proteins and fats, in the production of red blood cells, in the synthesis of nucleic acid components (deoxynucleoside) and in the metabolism of propionic acid.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium Dihydrogen Phosphate dihydrate
Sodium Chloride
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 of the immediate packaging: 28 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

100 ml amber, type II multidose glass vial, sealed with a bromobutyl rubber bung.

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4116

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

5th August 1993

10. DATE OF REVISION OF THE TEXT

August 2008