

## 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:

##### Qualitative

Cyanocobalamin (Vitamin B<sub>12</sub>)

##### Quantitative

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 B<sub>12</sub>) 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**

5<sup>th</sup> August 1993

**10.    DATE OF REVISION OF THE TEXT**

August 2008