BAG LABEL

Chloromed 150 mg/g Premix for medicated feeding stuff for calves

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

Univet Ltd.
Tullyvin
Cootehill
Co. Cavan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chloromed 150 mg/g Premix for medicated feeding stuff for calves.
Chlortetracycline hydrochloride

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

Chloromed Premix is a coarse, yellow powder containing 150 mg chlortetracycline hydrochloride per g. Medium chain triglycerides, soya bean meal and colloidal anhydrous silica are included as excipients.

4. INDICATION(S)

The product is indicated in the treatment of respiratory disease in calves caused by *Pasteurella spp*., sensitive to chlortetracycline.

5. CONTRAINDICATIONS

Do not use in calves over 6 months of age and dairy cows.
Do not use in animals with known hypersensitivity to tetracycline.
Do not use in animals with severe liver and renal disorders.

6. ADVERSE REACTIONS

Chlortetracycline toxicity is low. If digestive disturbances do occur, treatment should be discontinued.
On rare occasions the following adverse reactions may occur: allergic reactions and photosensitivity; gastrointestinal disorders; disorders of the liver and the kidneys. If suspected adverse reactions occur, treatment should be discontinued.
Due to the possible incorporation of chlortetracycline, treatment of pregnant and newborn animals can lead to dysfunctional development of the skeleton and teeth in foetal and growing animals.

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

7. TARGET SPECIES

Calves (less than 6 months of age).

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

The recommended therapeutic dose is 20 mg per kg bodyweight daily i.e. 20 grams of Chloromed 150 mg/g Premix per 150 kg bodyweight.

For the preparation of the medicated feed the body weight of the animals to be treated and their actual intake of feed should be taken into account. To ensure the correct dosage and to avoid under-dosing, the body weight should be determined as accurately as possible. The required dose should be measured by suitably calibrated weighing equipment. During the treatment period, only feed medicated with the product should be supplied. To provide the required amount of active substance per kg medicated feed the premix has to be incorporated into the feed according to the following formula:

$$\frac{\text{... mg Chloromed/kg bw/day x Average bw (kg) of animals to be treated}}{\text{Average daily feed intake (kg/animal)}} = \text{... mg Chloromed/kg of feed}$$

Treatment should be continued for a period of seven days. If animals don't recover within 3 days after oral medication, diagnosis should be reconsidered and treatment should be changed, if necessary.

The uptake of medicated feed depends on the clinical condition of the animals. In order to achieve the correct dosage the chlortetracycline inclusion rate in feed should be adjusted for feed intake.

Pelleting should not be conducted at temperatures in excess of 70°C.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure the correct dosage and to avoid under-dosing, the body weight should be determined as accurately as possible.

10. WITHDRAWAL PERIOD

Calves:
Meat and offal: 35 days.
Milk: The product is contraindicated for use in adult ruminants and dairy cows and should therefore not be used in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25˚C.
Store in a dry place.
Store in the original container.
Protect from light.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening of the immediate packaging: 1 month
Shelf life after incorporation into meal or pelleted feed: 4 weeks (if stored below 25˚C)

12. SPECIAL WARNING(S)

Special warnings for each target species

The uptake of oral medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed, animals should be treated parenterally.

Special precautions for use in animals

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

Inappropriate use of the product may increase the prevalence of bacteria resistant to chlortetracycline and may decrease the effectiveness of treatment with related substances, due to the potential for cross-resistance.

Long term use of this product is not recommended as it may lead to the development of bacterial resistance.

User warnings

Handle this product with care to avoid exposure when incorporating into feed and administering medicated feed to the animals.

Take adequate measures to avoid dust formation when incorporating the veterinary medicinal product into feed.

Persons handling the product should do so in a mechanically ventilated area.

Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.

Wear protective gloves, overalls and approved safety glasses.

Direct contact of the veterinary medicinal product with the skin, the eyes and the mucous membranes should be avoided. In case of accidental exposure rinse abundantly with water.

Do not smoke, eat or drink when handling the veterinary medicinal product

Use during pregnancy, lactation or lay

Not applicable.

Interaction with other medicinal products and other forms of interaction

This product is not recommended for concurrent administration with any other oral medication.
Do not incorporate the product in feed overloaded with polyvalent cations such as Ca^{2+} and Fe^{3+} because the formation of chlortetracycline complexes with these cations is possible.
Do not administer together with antacids, kaolin and iron preparations and in conjunction with bactericidal antibiotics like beta-lactams.
The product should not be used in case of known resistance to other tetracyclines.

Overdose

Do not exceed the stated dose.

Chlortetracycline toxicity is low. If digestive disturbances do occur, treatment should be discontinued.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only – to be supplied only on veterinary prescription.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with
other veterinary medicinal products.

Packed in a 25 kg, white low density polyethylene bag in a triple layered paper bag.

Marketing Authorisation Number:
Batch number:
EXP:

Additional text for bag label for UK

A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.