LABELLING

BAG LABEL

Chloromed 150 mg/g Oral Powder 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 Oral Powder for Calves.
Chlortetracycline hydrochloride.

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

Chloromed is a yellow uniform powder, containing 150 mg chlortetracycline hydrochloride per g.

4. INDICATION(S)

Calves:
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

Cattle (Calves less than 6 months of age)

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

For oral administration.

The recommended therapeutic dose is 20 mg chlortetracycline per kg bodyweight (equivalent to 20 grams of Chloromed 150 mg/g Oral Powder per 150 kg bodyweight) per day administered for seven days. This should be given in a divided daily dose i.e. 10 g morning and 10 g evening.

The product should be administered to small quantities of feed for immediate consumption by individual animals. Larger groups should be treated with medicated feeding stuff.

The product should be mixed thoroughly into a part of the daily feed ration and should be administered prior to the feeding. It should be ensured that the calculated dose is completely taken up by the animals.

If animals don't recover within 3 days after oral medication, diagnosis should be reconsidered and treatment should be changed, if necessary.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Meat and offal: 10 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 the immediate packaging: 28 days

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

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Do not eat, drink or smoke while handling the product or medicated feed.
During preparation and administration of the medicated feed, skin contact with the product and inhalation of dust particles should be avoided.
Personal protective equipment consisting of protective overall, glasses, impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143) should be worn when handling the veterinary medicinal product.
Wash hands immediately after handling the product or medicated feed.
In the event of skin or eye contact, rinse immediately the affected area with large amounts of clean water. If irritation occurs, seek medical attention.
If you develop symptoms following exposure to the product such as skin rash, you should seek medical advice and show the present warning to the doctor. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

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 THI LABEL WAS LAST APPROVED

15. OTHER INFORMATION

In-feed use.

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.

1 kg, clear low density polyethylene bag laminated with metallised polyester.

Marketing Authorisation Number:
Batch Number:
EXP: