BAG LABEL

Chloromed 150 mg/g premix for medicated feeding stuff for Pigs

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 Pigs.
Chlortetracycline hydrochloride.

3. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

4. INDICATIONS

Pigs:
The product is indicated in the treatment of respiratory disease in pigs caused by micro-organisms sensitive to chlortetracycline.

5. CONTRAINDICATIONS

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.

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

See also Special Warnings

7. TARGET SPECIES

Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE 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. 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 hydrochloride inclusion rate in feed should be adjusted for feed intake.

For oral administration after incorporation in a feeding stuff by a facility licensed to medicate feed. 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 possible under-dosing, the bodyweight should be determined as accurately as possible.

10. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 6 days.

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.

Store in a dry place.
Store in the original container.
Protect from light.

Do not use after the expiry date stated on the label.

Shelf-life after first opening the immediate packaging: 28 days
Shelf life after incorporation into meal or pelleted feed: 4 weeks (if stored below 25˚C)

12. SPECIAL WARNING(S), IF NECESSARY

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

The product is efficient only against bacterial strains most sensitive to chlortetracycline. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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 adding to feed and administering medicated feed to the animals.
Take adequate measures to avoid dust formation when adding the product to feed.

Those 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.

Direct contact of the product with the skin, eyes and mucous membranes should be avoided.
Wear protective gloves, overalls and approved safety glasses.
In case of accidental exposure, wash area immediately with water.

Do not smoke, eat or drink when handling the product.
Hands and exposed skin should be washed thoroughly after use.

Use during pregnancy, lactation or lay

The use is not recommended during pregnancy or lactation. The treatment of pregnant animals with chlortetracycline may result in adverse effects on skeletal and tooth development in the foetus. Therefore, the product should be used only in pregnant sows according to the benefit/risk assessment of the responsible veterinarian.

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 PRODUCS OR WASTE MATERIALS, IF ANY

Any unused product or waste materials should be disposed of in accordance with national requirements.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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

15. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

17. OTHER INFORMATION

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

Marketing Authorisation Number:
Batch Number:
EXP: (month/year)

Approved: 03 June 2016