BAG LABEL

Chloromed 150 mg/g Oral Powder 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 Oral Powder 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 tetracyclines or any of the excipients.
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 (more than 1 but less than 10 animals in 10,000 animals) 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

For oral administration.

The recommended therapeutic dose is 20 mg chlortetracycline hydrochloride 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. As a guide to dosing pigs of different weight, see table.

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 animal.

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 and the amount of product administered should be determined as accurately as possible. To determine the correct amount of product, a calibrated weighing scale should be used.

Dosing Table

Pig Bodyweight (kg)	Daily amount (g) of Chloromed 150	Dose (g) – to be given TWICE daily
15 kg	2g	1g
30 kg	4g	2g
60 kg	8g	4g
75 kg	10g	5g
150 kg	20g	10g

10. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 6 days.

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.
Store in the original container.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP". 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), 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.

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

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 add the product to 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.

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 veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local 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 sight and reach of children.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

17. OTHER INFORMATION

In-feed use.
1 kg, clear low density polyethylene bag laminated with metallised polyester.
Once opened, use by:….

[*Additional text for Ireland and UK*
When the container is opened for the first time, using the in-use shelf-life which is specified on the label, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided.]

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