MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London

EC4A 3AE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetramin 200 Powder Premix for Medicated Feed

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

A medicated feed premix containing 200 g of oxytetracycline (as the dihydrate) per kg of product.

4. PHARMACEUTICAL FORM

Premix for medicated feed

5. PACKAGE SIZE

25 kg

6. INDICATION(S)

For use as an aid in the control of respiratory diseases caused by bacteria sensitive to oxytetracycline.

7. CONTRAINDICATIONS

None

8. ADVERSE REACTIONS

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9. TARGET SPECIES

For use in pigs only (with bodyweights in the range 5 to 90 kg).

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

The dose is 20 mg of oxytetracycline dihydrate per kilogram of bodyweight, administered for a period of 15 days. At normal feed intakes this dose may be achieved by the addition of 2 kg of the product per 1000 kg of feed.

The following inclusion rates may be used as a guide to obtaining the recommended dose of 20 mg of oxytetracycline dihydrate per kilogram of bodyweight in normal and inappetant pigs.

11. ADVICE ON CORRECT ADMINISTRATION

Food intake expressed as a percentage of animal bodyweight	Inclusion rate, kg of product per 1000kg of feed
5% (normal)	2 kg
4% (inappetant)	2.5 kg
3% (inappetant)	3.25 kg
2% (inappetant)	5 kg

Incorporation in feed must be in accordance with the terms of the Marketing Authorisation (as stated above) or in accordance with a Medicated Feedingstuffs Prescription.

To ensure thorough dispersion of the product it should first be mixed with a suitable quantity of feed before incorporation in the final mix. If the product is incorporated into an intermediate feeding-stuff, care should be taken to ensure that the final incorporation of the intermediate in finished feed yields the correct concentration of active ingredient as stated in the dosage schedule.

12. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Pigs may be slaughtered for human consumption only after 5 days from the end of last treatment.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place. Protect from light.

The product is stable during pelleting and in pelleted and unpelleted feed for up to 3 months and in protein concentrates and vitamin/mineral premixes for 6 months.

14. SPECIAL WARNING(S)

If you know you are allergic to oxytetracycline, do not handle the product. When incorporating into feed, care should be taken not to inhale any dust when handling the product and skin contact should be avoided. It is recommended that a face mask, conforming to EN140 with a filter to EN143, be worn during the dispensing of the

product. Hands and exposed skin should be washed thoroughly at the end of the operation.

Long term use of this product may lead to development of bacterial resistance and is not recommended. However, the recommended course of treatment should be completed.

15. EXPIRY DATE

Exp:

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

POM-V

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4153

21. MANUFACTURER'S BATCH NUMBER

Lot:

22. OTHER INFORMATION

Approved: 18/01/2018