PARTICULARS TO APPEAR ON THE OUTER PACKAGE (3 kg and 25 kg)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurofac® Granular 100 mg/g Premix for Medicated Feeding Stuff

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

PARTICULARS TO APPEAR ON OUTER CARTON (8 X 3KG)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurofac® Granular 100 mg/g Premix for Medicated Feeding Stuff

2. RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

To be supplied only on veterinary prescription

3. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

4. MARKETING AUTHORISATION NUMBER

Vm 42058/4007

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels.

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

MA Holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer:
Zoetis Medolla Manufacturing S.r.l.
Via Rubadello 6
I-41036 Medolla
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aurofac® Granular 100 mg/g Premix for Medicated Feeding Stuff

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

A dark yellow granular premix containing 100 g of chlortetracycline hydrochloride per kg.

4. PHARMACEUTICAL FORM

Premix for Medicated Feeding Stuff

5. PACKAGE SIZE

Net weight:
3 kg
25 kg

6. INDICATION(S)

For oral administration via the feed for treatment and control of respiratory and systemic infections associated with organisms sensitive to chlortetracycline in pigs, chickens, turkeys, ducks.

7. CONTRAINDICATIONS

Do not use in ruminants.

8. ADVERSE REACTIONS

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9. TARGET SPECIES

Pigs, Chickens, Turkeys, Ducks

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

The following dosages should be respected:
Pigs: 10-20 mg/kg bodyweight
Chickens: 20-30 mg/kg bodyweight
Turkeys: 10-30 mg/kg bodyweight
Ducks: 10-30 mg/kg bodyweight

11. ADVICE ON CORRECT ADMINISTRATION

Official, national and regional antimicrobial policies should be taken into account when the product is used.

These dose rates can usually be achieved by mixing 3.0 kg of Aurofac® Granular 100 mg/g Premix for Medicated Feeding Stuff per tonne of complete feed to give a concentration of 300 ppm chlortetracycline hydrochloride. However, the correct incorporation rate should always be calculated based on the feed consumption rates of the animals to be treated.

The medicated feed should be supplied to the affected pen(s) or group(s) of pigs, chickens, turkeys or ducks. Treatment should be continued for a period of five to seven days for respiratory or systemic infections. During the treatment period, only feed medicated with Aurofac® Granular 100 mg/g Premix for Medicated Feeding Stuff should be supplied.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of chlortetracycline has to be adjusted accordingly.

For incorporation intro dry feed at the registered mill. 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 of final feed.

12. WITHDRAWAL PERIOD

The following withdrawal periods should be respected:
Pigs (meat): 10 days
Chickens/Turkeys (meat): 2 days
Ducks (meat): 4 days
Chickens/Turkeys/Ducks (eggs): contraindicated
Animals must not be slaughtered for human consumption during treatment.

13. PHARMACEUTICAL PRECAUTIONS

Do not store above 30°C. After first opening the bag of premix, any remaining contents should be stored in a dry place and the bag should be closed and secured with a suitable bag tie.

After opening the product can be used for 14 days. When the bag is opened for the first time, the date on which any product remaining in the bag should be discarded should be worked out. This discard date should be written in the space provided on the label (cover page). Store apart from animal feeding stuffs. To ensure thorough dispersion of the product, it should be first mixed with a suitable quantity of feed ingredients before incorporation into the final mix.

Aurofac® Granular 100 mg/g Premix for Medicated Feeding Stuff can be incorporated in pelleted feed preconditioned at temperatures up to 70°C.

Aurofac® Granular 100 mg/g Premix for Medicated Feeding Stuff will remain stable in the finished mash feed for 2 months and in pelleted feed for 3 weeks.

14. SPECIAL WARNING(S)

Operator Warnings:
If you know you are hypersensitive (allergic) to chlortetracycline, do not handle the product. When handling this product, inhalation of the dust must be avoided by wearing a disposable half-mask respirator conforming to European Standard EN 149 or a nondisposable respirator to European Standard EN 140 with a filter to EN 143.

Avoid contact with skin and eyes. Gloves should be worn whilst handling this product. If contact with skin or eyes occurs, wash area immediately with clean fresh water. If irritation persists seek medical attention.

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

15. EXPIRY DATE

Use by end: MM.YYYY

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

Disposal advice
Dispose of any unused product or waste material derived from it in accordance with guidance from your local waste regulation authority.

Discard date:

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

August 2020

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

For animal treatment only

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

Keep out of reach of children.

20. MARKETING AUTHORISATION NUMBER

Vm 42058/4007

21. MANUFACTURER'S BATCH NUMBER

Batch number:

22. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

Product code:

Production date:

Approved 21 August 2020