PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Occrycetin® Bolus

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: Oxytetracycline Hydrochloride 500 mg

500 mg Tablet

3. PHARMACEUTICAL FORM

Bolus

4. PACKAGE SIZE

20 Tablets

5. TARGET SPECIES

Calves

6. INDICATION(S)

For gastro-intestinal infections in calves caused by gram-positive and gram-negative pathogenic bacteria sensitive to oxytetracycline

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose:

Oral: One tablet per 50 kg (10 mg/kg) twice daily for approximately 5 days.

For full information see enclosed leaflet.

8. WITHDRAWAL PERIOD

Calves must not be slaughtered for human consumption during treatment and for 14 days afterwards.

9. SPECIAL WARNING(S), IF NECESSARY

Wash hands after use.

This product must not be used in calves with functional rumens. Neither should it be used when there is known hypersensitivity to Oxytetracycline.

The use of tetracyclines during the period of tooth development, including pregnancy, may lead to tooth discolouration.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

-

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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4087

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Occrycetin® Bolus 500 mg Tablet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: Oxytetracycline Hydrochloride 500 mg

3. PHARMACEUTICAL FORM

Bolus

4. PACKAGE SIZE

20 Tablets

5. TARGET SPECIES

Calves

6. INDICATION(S)

For gastro-intestinal infections in calves caused by gram-positive and gram-negative pathogenic bacteria sensitive to oxytetracycline.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose:

Oral: One tablet per 50 kg (10 mg/kg) twice daily for approximately 5 days.

For full information see enclosed leaflet.

8. WITHDRAWAL PERIOD

Calves must not be slaughtered for human consumption during treatment and for 14 days afterwards.

9. SPECIAL WARNING(S), IF NECESSARY

Wash hands after use.

This product must not be used in calves with functional rumens. Neither should it be used when there is known hypersensitivity to Oxytetracycline.

The use of tetracyclines during the period of tooth development, including pregnancy, may lead to tooth discolouration.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

-

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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4087

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Occrycetin® Bolus 500 mg Tablet

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

Batch release site not currently listed

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Occrycetin® Bolus 500 mg Tablet

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Occrycetin Bolus are orange, ovaloid tablets with a characteristic bolus shape and a deep scored break-line on one face.

Each tablet contains Oxytetracycline Hydrochloride 500 mg.

4. INDICATIONS

Occrycetin Bolus can be used for the treatment of gastro-intestinal infections in calves caused by both gram-positive and gram-negative pathogenic bacteria sensitive to oxytetracycline.

5. CONTRAINDICATIONS

This product must not be used in calves with functional rumens. Neither should it be used when there is known hypersensitivity to oxytetracycline.

The use of tetracyclines during the period of tooth development, including pregnancy, may lead to tooth discolouration.

6. ADVERSE REACTIONS

-

7. TARGET SPECIES

Calves

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

Oral: Dosage must be determined by the severity of the case but in general the following dosage is recommended.

Calves: 1 tablet per 50 kg (10 mg/kg) bodyweight twice daily. Treatment should be continued for approximately 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

The tablet may be given either whole or crushed.

10. WITHDRAWAL PERIOD

Calves must not be slaughtered for human consumption during treatment and for 14 days afterwards.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

12. SPECIAL WARNING

User Warnings

In the event of accidental ingestion, immediately flush mouth with water. Seek medical attention taking this warning to show your doctor. In the event of contact with the eyes, flush with plenty of water.

If irritation persists seek medical attention.

Wash hands after use.

For animal treatment only

Keep out of reach and sight of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Not currently stated

15. OTHER INFORMATION

In very severe conditions, the concurrent administration of oxytetracycline hydrochloride by deep intramuscular injection may also be considered desirable.

Box of 20 tablets.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4087

Approved: 09/08/2017