PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON CHLORSOL 50% POWDER FOR ORAL SOLUTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chlorsol 50% Powder for Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Chlortetracycline hydrochloride Ph. Eur. 50%

3. PHARMACEUTICAL FORM

Powder for oral solution

4. PACKAGE SIZE

Carton of 20 x 200g sachets

5. TARGET SPECIES

Chickens and pigs

6. INDICATION(S)

Chlorsol 50 is administered to broiler chickens and pigs for the treatment of infections due to susceptible bacteria.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Chlorsol 50 is recommended for oral administration in drinking water.

Chickens: 200g of product should be dissolved in 600L drinking water and administered daily for up to 5 days. This will provide a daily dosage of 20.50 mg Chlortetracycline HCl/kg depending on water consumption. Dosage may be adjusted to up to 60mg/kg depending on the severity of the infection, by careful calculation of the total bodyweight of the birds and dissolving the requisite amount of Chlorsol 50 in the quantity of water consumed within 24 hours.

Pigs: In order to achieve the recommended dosage rate of 20mg Chlortetracycline HCl/kg, 200g of the product should be dissolved in 500L of water and administered for up to 5 days. This will provide medication for 5000 kg of pigs. Allowance for wastage of medicated water and reduced water intake should be made and the necessary adjustment made to the amount of product used. Chicken and pigs should have access only to medicated water during treatment. Medicated water should be prepared daily and any not consumed within 24 hours discarded safely.

8. WITHDRAWAL PERIOD

Chickens must not be slaughtered for human consumption within 3 days of last treatment. Pigs must not be slaughtered for human consumption within 6 days of the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to hens producing eggs for human consumption or pregnant sows. Dispose of any medicated water with manure or slurry. Dispose of any unused product or waste material in accordance with national requirements. Absorption of chlortetracycline from the alimentary tract is reduced by calcium, magnesium, iron and zinc salts.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

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

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

Unused product should be disposed of in accordance with national requirements.

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

User Information

Once opened, the entire contents of the sachet must be added to the required quantity of water. Avoid inhalation of the dust by wearing a protective mask. Wear either a disposable half mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143. In case of accidental spillage on to the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation occurs/persists. Wash hands thoroughly after using this product.

For animal treatment only. Prescription only medicine.

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Veterinary Medicinal Product authorised for use in UK and IE. To be supplied only on veterinary prescription.

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol Biowet, Gorzow Wlkp, Poland

Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton Towcester Northamptonshire NN12 7LS

16. MARKETING AUTHORISATION NUMBERS

Vm 08007/4052

VPA 10966/11/1

17. MANUFACTURER'S BATCH NUMBER

Batch No .:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL

CHLORSOL 50% POWDER FOR ORAL SOLUTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chlorsol 50% Powder for Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Chlortetracycline Hydrochloride Ph.Eur 50%

3. PHARMACEUTICAL FORM

Powder for Oral Solution

4. PACKAGE SIZE

Sachet of 2kg

5. TARGET SPECIES

Chickens and pigs

6. INDICATIONS

Chlorsol 50 is administered to broiler chickens and pigs for the treatment of infections due to susceptible bacteria.

7. METHOD AND ROUTE OF ADMINISTRATION

Chlorsol 50 is recommended for oral administration in drinking water.

Chickens: 200g of product should be dissolved in 600L drinking water and administered daily for up to 5 days. This will provide a daily dosage of 20-50 mg Chlortetracycline HCl/kg depending on water consumption. Dosage may be adjusted to up to 60mg/kg depending on the severity of the infection, by careful calculation of the total bodyweight of the birds and dissolving the requisite amount of Chlorsol 50 in the quantity of water consumed within 24 hours.

Pigs: In order to achieve the recommended dosage rate of 20mg Chlortetracycline HCl/kg, 200g of the product should be dissolved in 500L of water and administered for up to 5 days. This will provide medication for 5000 kg of pigs. Allowance for wastage of medicated water and reduced water intake should be made and the necessary adjustment made to the amount of product used. Chicken and pigs should have access only to medicated water during treatment. Following initial opening and calculated date of discard should be written in the space provided on the label. 1 level 25ml scoop contains approximately 20g of powder.

8. WITHDRAWAL PERIOD

Chickens must not be slaughtered for human consumption within 3 days of last treatment. Pigs must not be slaughtered for human consumption within 6 days of the last treatment.

9. SPECIAL WARNINGS, IF NECESSARY

Do not administer to hens producing eggs for human consumption or pregnant sows. Dispose of any medicated water with manure or slurry. Dispose of any unused product or waste material in accordance with national requirements. Absorption of chlortetracycline from the alimentary tract is reduced by calcium, magnesium, iron and zinc salts.

10. EXPIRY DATE

Expiry date .:

11. SPECIAL STORAGE CONDITIONS

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

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

Medicated water should be prepared daily and any not consumed within 24 hours discarded safely. Date of Opening: Date of Discard:

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

User Information:

Avoid inhalation of the dust by wearing a protective mask. Wear either a disposable half mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143. In case of accidental spillage on to the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation occurs/persists. Wash hands thoroughly after using this product.

For animal treatment only. Prescription only medicine.

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by: Vetoquinol Biowet, Gorzow Wlkp, Poland

Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton Towcester Northamptonshire NN12 7LS

16. MARKETING AUTHORISATION NUMBERS

Vm 08007/4052

VPA 10966/11/1

17. MANUFACTURER'S BATCH NUMBER

Batch No .:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - SACHET

CHLORSOL 50% POWDER FOR ORAL SOLUTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chlorsol 50% Powder for Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Chlortetracycline Hydrochloride Ph.Eur 50%

3. PHARMACEUTICAL FORM

Powder for Oral Solution

4. PACKAGE SIZE

Sachet of 200g

5. TARGET SPECIES

Chickens and pigs.

6. INDICATIONS

Chlorsol 50 is administered to broiler chickens and pigs for the treatment of infections due to susceptible bacteria.

7. METHOD AND ROUTE OF ADMINISTRATION

Chlorsol 50 is recommended for oral administration in drinking water. **Chickens:** 200g of product should be dissolved in 600L drinking water and administered daily for up to 5 days. This will provide a daily dosage of 20.50 mg Chlortetracycline HCl/kg depending on water consumption. Dosage may be adjusted to up to 60mg/kg depending on the severity of the infection, by careful calculation of the total bodyweight of the birds and dissolving the requisite amount of Chlorsol 50 in the quantity of water consumed within 24 hours. **Pigs:** In order to achieve the recommended dosage rate of 20mg Chlortetracycline HCl/kg, 200g of the product should be dissolved in 500L of water and administered for up to 5 days. This will provide medication for 5000 kg of pigs. Allowance for wastage of medicated water and reduced water intake should be made and the necessary adjustment made to the amount of product used. Chicken and pigs should have access only to medicated water during treatment. Once opened, the entire contents of the sachet must be added to the required quantity of water.

8. WITHDRAWAL PERIOD

Chickens must not be slaughtered for human consumption within 3 days of last treatment. Pigs must not be slaughtered for human consumption within 6 days of the last treatment.

9. SPECIAL WARNINGS, IF NECESSARY

Do not administer to hens producing eggs for human consumption or pregnant sows.. Any medicated water which is not consumed within 24 hours should be discarded safely. Absorption of chlortetracycline from the alimentary tract is reduced by calcium, magnesium, iron and zinc salts.

10. EXPIRY DATE

Expiry date.

11. SPECIAL STORAGE CONDITIONS

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

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

Medicated water should be prepared daily and any not consumed within 24 hours discarded safely.

Dispose of any medicated water with manure or slurry. Dispose of any unused product or waste materials in accordance with national requirements.

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

User Information:

Avoid inhalation of the dust by wearing a protective mask. Wear either a disposable half mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143. In case of accidental spillage on to the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation occurs/persists. Wash hands thoroughly after using this product.

For animal treatment only.

Prescription only medicine.

Veterinary Medical Product authorised for use in UK and IE. To be supplied only on Veterinary prescription.

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by: Vetoquinol Biowet Sp. z o.o. Gorzow Wlkp, Poland

Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton Towcester Northamptonshire NN12 7LS

16. MARKETING AUTHORISATION NUMBERS

Vm 08007/4052

VPA 10966/11/1

17. MANUFACTURER'S BATCH NUMBER

Batch No:

Approved: 02 May 2018

D. Austro-