PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton text - 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetroxy Vet 200 mg/ml solution for injection for cattle, sheep and pigs.
Oxytetracycline Dihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Active Substance:
One ml contains:
Oxytetracycline (as dihydrate) 200.0 mg
(equivalent to 216 mg oxytetracycline dihydrate)
Excipient:
Sodium Formaldehyde Sulphoxylate Dihydrate 4.0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal Period:
Cattle:
Meat and offal: 31 days
Milk: 10 days (210 hours)

Sheep:
Meat and offal: 9 days
Milk: 7 days (168 hours)

Pigs:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Pregnant women and women of child bearing age should exercise caution when handling this product – read package leaflet before use.

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 28 days.
Once broached, use by _____.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. 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.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

VPA 22033/068/001 (IE)
Vm 50146/4008 (UK)
402202.00.00 (DE)
FR/V/2824223 9/15 (FR)
3380 ESP (ES)

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label text - 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetroxy Vet 200 mg/ml solution for injection for cattle, sheep and pigs.

Oxytetracycline Dihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

One ml contains:
Oxytetracycline (as dihydrate) 200.0 mg
(equivalent to 216 mg oxytetracycline dihydrate)
Excipient:
Sodium Formaldehyde Sulphoxylate Dihydrate 4.0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal Period:
Cattle:
Meat and offal: 31 days
Milk: 10 days (240 hours)

Sheep:
Meat and offal: 9 days
Milk: 7 days (168 hours)

Pigs:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 28 days.
Once broached, use by _____.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

12. SPECIAL 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

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

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

VPA 22033/068/001 (IE)

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402202.00.00 (DE)
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3380 ESP (ES)

17. MANUFACTURER'S BATCH NUMBER

Batch

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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetroxy Vet 200 mg/ml solution for injection for cattle, sheep and pigs.

Oxytetracycline Dihydrate

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

A clear amber solution for injection.

Active Substance:
One ml contains:
Oxytetracycline (as dihydrate) 200.0 mg
(Equivalent to 216 mg oxytetracycline dihydrate)

Excipients:
Sodium Formaldehyde Sulphoxylate Dihydrate 4.0mg,

4. INDICATION(S)

Treatment of infections caused by oxytetracycline susceptible bacteria in cattle, sheep and pigs as follows:

Cattle:
- Pasteurellosis and respiratory tract infections caused by *Mannheimia haemolytica* or *Pasteurella multocida*.
- Umbilical infections and septic arthritis caused by *Trueperella pyogenes*, *Escherichia coli* or *Staphylococcus aureus*.
- Clinical Mastitis caused by *Trueperella pyogenes*, *Escherichia coli*, *Staphylococcus aureus, Streptococcus agalactiae* or *Streptococcus uberis*.
- Metritis caused by *Escherichia coli*

Sheep:
- Pasteurellosis and respiratory tract infections caused by *Mannheimia haemolytica* or *Pasteurella multocida*.
- Umbilical infections and septic arthritis caused by *Trueperella pyogenes*- or *Escherichia coli*.

- Clinical Mastitis caused by *Trueperella pyogenes*, *Escherichia coli* or *Staphylococcus aureus.*
- Erysipelas caused by *Erysipelothrix rhusiopathiae*.
- The product can also be used for treatment and metaphylaxis of enzootic abortion in sheep caused by *Chlamydophila abortus*. The presence of the disease in the group must be established before the product is used.

Pigs:

- Pasteurellosis and respiratory tract infections caused by *Mannheimia haemolytica* or *Pasteurella multocida*.
- Umbilical infections and septic arthritis caused by *Trueperella pyogenes*, *Escherichia coli* or *Staphylococcus aureus*.
- Clinical Mastitis caused by *Escherichia coli.*
- Erysipelas caused by *Erysipelothrix rhusiopathiae*.
- Atrophic rhinitis caused by *Bordetella bronchiseptica* or *Pasteurella multocida*.

5. CONTRAINDICATIONS

Do not use in horses, dogs and cats.
Do not use in animals with hepatic or renal damage.
Do not use in known cases of hypersensitivity to the active substance, to other tetracyclines or to any of the excipients.
Do not use in known cases of resistance to tetracyclines.

6. ADVERSE REACTIONS

Occasionally a slight local reaction of a transient nature has been observed.

Tetracyclines have very rarely been associated with photosensitivity reactions and, rarely, hepatotoxicity and blood dyscrasias.

Oxytetracycline given to young animals can cause a yellow, brown or grey discolouration of bones and teeth. High dose or chronic administration may delay bone growth or healing.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Cattle, sheep and pigs.

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

Deep intramuscular administration. The recommended dose rate is 20 mg of oxytetracycline/kg bodyweight (i.e. 1 mL of product per 10 kg bodyweight). The product is recommended for a single administration only.
The cap may be safely punctured up to 35 times. When treating groups of animals, use a draw-off needle.

Maximum volume to be administered per injection site:

Cattle : 20ml
Pigs : 10ml
Sheep: 5ml

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 31 days
Milk: 10 days (240 hours)

Sheep:
Meat and offal: 9 days
Milk: 7 days (168 hours)

Pigs:
Meat and offal: 18 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.
Do not store above 25ºC.
Keep the vial in the outer carton in order to protect from light.
Shelf life after first opening the immediate packaging: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
For animal treatment only.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

Do not dilute the product.
If concurrent treatment is administered, use a separate injection site.
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.
Official and local antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to oxytetracycline and may decrease the effectiveness of treatment with other tetracyclines due to the potential for cross-resistance.

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

This product may cause sensitisation.
People with known hypersensitivity to tetracyclines, such as oxytetracycline, should avoid contact with the product.
This product may cause skin and eye irritation.
Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.
Take care to avoid accidental injection. In case of self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
The excipient dimethylacetamide may damage the unborn child; therefore, women of child bearing age must be very careful to avoid exposure via spillage onto the skin or accidental self-injection when administering the product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product.

Use during pregnancy, lactation, lay:

The product can be used during lactation.
The active substance, oxytetracycline, readily crosses the placenta and concentrations in the foetal blood may reach those of the maternal circulation, although the concentration is usually somewhat lower. Tetracyclines are deposited in teeth, causing discolouration, enamel hypoplasia and reduced mineralisation. Tetracyclines can also delay foetal skeletal development. As such, the product should only be used in the last half of pregnancy following risk benefit assessment by the responsible veterinarian.
Oxytetracycline is excreted in milk; concentrations are generally low.

Interaction with other medicinal products and other forms of interaction:

Oxytetracycline should not be administered simultaneously with bactericidal antimicrobials, such as penicillins and cephalosporins.
Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines.

Overdose (symptoms, emergency procedures, antidotes):

There is no known specific antidote, if signs of possible overdose occur treat the animal symptomatically.

Major incompatibilities:

The product should not be mixed with other veterinary medicinal products.

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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

Package quantities: 100 ml containers.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Bimeda ®
Cross Vetpharm Group UK Ltd.
Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA
United Kingdom

Authorisation Number:

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POM Prescription Only Medicine. To be supplied only on veterinary prescription.

Approved: 03/03/21