ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON – 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetroxy LA 200 mg/ml solution for injection for cattle, sheep and pigs
Oxytetracycline

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Oxytetracycline 200 mg/ml

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

Solution for injection.
Read the package leaflet before use.
The recommended dose rate is 20 mg/kg bodyweight (i.e. 1 ml per 10 kg bodyweight) administered by deep intramuscular injection. To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
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 : 20 ml
Pigs : 10 ml
Sheep: 5 ml

8. WITHDRAWAL PERIOD

Withdrawal Period:
Cattle:
Meat and offal: 31 days
Milk: 10 days

Sheep:
Meat and offal: 9 days
Milk: 7 days
Pigs:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
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

Vm 50146/4021

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL – 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetroxy LA 200 mg/ml solution for injection for cattle, sheep and pigs
Oxytetracycline

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Oxytetracycline 200 mg/ml

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

Solution for injection.
Read the package leaflet before use.
The recommended dose rate is 20 mg/kg bodyweight (i.e. 1 ml per 10 kg bodyweight) administered by deep intramuscular injection. To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
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 : 20 ml
Pigs : 10 ml
Sheep: 5 ml

8. WITHDRAWAL PERIOD

Withdrawal Period:
Cattle:
Meat and offal: 31 days
Milk: 10 days
Sheep:
Meat and offal: 9 days
Milk: 7 days
Pigs:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
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"

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

Vm 50146/4021

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE INSERT

PACKAGE LEAFLET FOR:
Vetroxy LA 200 mg/ml solution for injection for cattle, sheep and pigs

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

Marketing authorisation holder:
Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght,
Dublin 24
Ireland

Manufacturer responsible for batch release:
Dopharma B.V
Zalmweg 24, Raamsdonksveer,
4941 VX
Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetroxy LA 200 mg/ml solution for injection for cattle, sheep and pigs.

Oxytetracycline

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

A clear amber solution for injection.

1 ml contains:

Active Substance:
Oxytetracycline 200 mg

Excipient:
Sodium formaldehyde sulfoxylate dihydrate 4.0 mg

4. INDICATION(S)

The product is indicated for the 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*.

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 cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Although the product is well tolerated, very rarely a slight local reaction of a transient nature has been observed.

Tetracyclines have also been associated with photosensitivity reactions and, rarely, with 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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}. For details regarding the national system please contact NCA.

7. TARGET SPECIES

Cattle, sheep and pigs.

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

The recommended dose rate is 20 mg/kg bodyweight (i.e. 1 ml per 10 kg bodyweight) administered by deep intramuscular injection. 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.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
Maximum volume to be administered per injection site:

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

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 31 days
Milk: 10 days

Sheep:
Meat and offal: 9 days
Milk: 7 days
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 after 'EXP'. The expiry date refers to the last day of that month.

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:

The excipient dimethylacetamide may damage unborn children; 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.
This product may cause allergy-type reactions in sensitised people.
Those with known hypersensitivity to tetracyclines 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.

Pregnancy and lactation

The safety of the veterinary medicinal product has not been tested in the target

species.
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 retard foetal skeletal development. As such, the product should only be used in the last half of pregnancy when the benefits outweigh the foetal risks.

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.
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

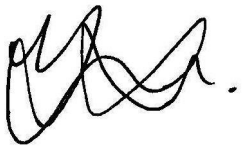
Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

Package quantities: 100 ml containers.



Approved: 29 February 2024