PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytetrin™ 20 LA 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 200mg/ml oxytetracycline as Oxytetracycline Dihydrate and formulated in polyvinylpyrrolidone.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

cattle, sheep and pigs

6. INDICATION(S)

For the treatment and control of diseases in cattle, sheep and pigs caused by or associated with organisms sensitive to oxytetracycline.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection.

CATTLE	SHEEP	PIGS
Dose ml/10kg bodyweight		

1 ml/10kg		
Maximum dose volume per site		
10ml	**10ml**	**5ml**

8. WITHDRAWAL PERIOD

CATTLE	**SHEEP**	**PIGS**
Meat withdrawal period		
39 days	**28 days**	**40 days**

9. SPECIAL WARNING(S), IF NECESSARY

This product is not for use in animals producing milk for human consumption. Animals may only be slaughtered for human consumption after last treatment according to the table opposite.

Operator warnings:

Wash hands after use.Avoid contact with eyes.

10. EXPIRY DATE

Date of Broaching: _____ / ____ / ____

Date of Discard: _____ / ____ / ____

USE BY:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°c. Protect from light. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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

Discard unused material.

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

POM-V

To be supplied only on veterinary prescription.

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

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder

Intervet UK Ltd

Walton Manor, Walton

Milton Keynes

MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4563

17. MANUFACTURER'S BATCH NUMBER

LOT NO:

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

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

Marketing Authorisation Holder

Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, MK7 7AJ, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytetrin™ 20 LA 200 mg/ml Solution for Injection

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

A clear sterile, yellow to amber, coloured aqueous solution containing 200mg/ml oxytetracycline as Oxytetracline Dihydrate and Polyvinylpyrrolidone.

4. INDICATION(S)

Oxytetrin 20 LA is indicated in the treatment and control of diseases in cattle, sheep and pigs caused by, or associated with, organisms sensitive to oxytetracycline. Following intramuscular injection of Oxytetrin 20 LA, effective blood levels are maintained for up to 72 hours in cattle and 48 hours in pigs and sheep.

5. CONTRAINDICATIONS

Not recommended for cats, dogs, horses and donkeys. Do not use in animals producing milk for human consumption. The use of the product during the period of tooth development including late pregnancy may lead to tooth discolouration.

Protection of consumers

This product is not for use in animals producing milk for human consumption**.**

Animals may only be slaughtered for human consumption after last treatment according to the table below.

Species	Meat withdrawal period
Cattle	39 days
Sheep	28 days
Pigs	40days

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

6. ADVERSE REACTIONS

7. TARGET SPECIES

cattle, sheep and pigs

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

Dosage and administration:

By deep intramuscular injection.

Normal aseptic precautions should be observed.

Species:	Dose (ml/10kg bodyweight)	Max volume at one injection site
Cattle, Sheep	1ml/10kg	10 ml
Pigs	1ml/10kg	5 ml

Pigs under 10kg: maximum dose 1ml.

Because of the sustained blood levels attained at the above dosage rates with Oxytetrin 20 LA one treatment is usually sufficient.

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Species	Meat withdrawal period
Cattle	39 days
Sheep	28 days
Pigs	40days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

Following withdrawal of the first dose, use the product within 28 days. When the container is broached (opened) for the first time, the date on which any remaining in the container should be discarded should be calculated.

A statement of the in-use shelf-life of the product is given on the package leaflet. This discard date should be written on the space provided on the label.

The product should not be brought into contact with calcium solutions. Do not dilute.

12. SPECIAL WARNING(S)

Operator warnings

Wash hands after use.

Avoid contact with the eyes.

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

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

11 April 2012

<15. OTHER INFORMATION>

POM-V

To be supplied only on veterinary prescription

Vm 01708/4563

Package quantities:

Multidose vials of 100ml.

Approved: 10/07/2017