PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacycline LA 20% Solution for Injection

Oxytetracycline

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Oxytetracycline Dihydrate PhEur equivalent to 200 mg Oxytetracycline base as the magnesium complex and 4mg Sodium Formaldehyde Sulphoxylate USNF (antioxidant) in an aqueous solution.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, pigs and sheep

6. INDICATION(S)

Duphacycline LA is indicated for the treatment and control of conditions caused by or associated with organisms susceptible to the action of oxytetracycline.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By deep intramuscular injection to cattle, pigs and sheep

Dosage: 1 ml per 10 kg bodyweight.

For use: See package leaflet.

400 kg (cow icon) 40 ml

50 kg (sheep icon) 5 ml

50 kg (pig icon) 5 ml

8. WITHDRAWAL PERIOD

Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 10 days from the last treatment. Milk for human consumption may be taken from sheep only after 7 days from the last treatment. Animals must not be slaughtered for human consumption during

treatment. Cattle may be slaughtered for human consumption only after 31 days from the last treatment. Pigs may be slaughtered for human consumption only after 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 9 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Not for use in animals suffering from renal or hepatic damage.

Wash hands after use. In case of contact with eyes or skin, wash immediately with water as irritation may occur. Avoid contact with eyes.

Not recommended for cats, dogs and horses.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Do not dilute.

Following withdrawal of the first dose, use within 28 days. Discard unused material.

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

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

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

POM-V

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

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London

EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4039

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Duphacycline LA Oxtetracycline 20% Solution For Injection

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacycline LA 20% Solution for Injection

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

Aqueous solution for injection containing Oxytetracycline Dihydrate PhEur equivalent to 200 mg/ml oxytetracycline base and 4mg/ml Sodium Formaldehyde Sulphoxylate USNF (antioxidant).

4. INDICATION(S)

USES

Oxytetracycline is a bacteriostatic antibiotic active against a wide range of Gram-positive and Gram-negative bacteria. Following intramuscular injection peak blood levels are achieved within 4 to 8 hours for the treatment of acute infections. Blood levels then persist for at least 4 days to give prolonged activity.

Duphacycline LA is indicated for the treatment and control of diseases caused by organisms sensitive to oxytetracycline in cattle, sheep and pigs. These include *Bordetella bronchiseptica, Actinomyces pyogenes, Erysipelothrix rhusiopathiae, Escherichia coli, Haemophilus somnus, Mannheimia haemolytica, Pasteurella multocida, Salmonella dublin, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes* and *Streptococcus uberis.*

Duphacycline LA is indicated in the treatment of atrophic rhinitis caused by *Bordetella bronchiseptica, Pasteurella haemolytica* and *Mannheimia multocida.* Navel/joint ill caused by *Actinomyces pyogenes, E. coli* and *Staphylococcus aureus.* Mastitis caused by *Actinomyces pyogenes, E. coli, Staphylococcus aureus, Streptococcus agalactiae* and *Streptococcus uberis.* Metritis caused by *E. coli* and *Streptococcus pyogenes.* Pasteurellosis and infections of the respiratory tract caused by *Mannheimia haemolytica* and *Pasteurella multocida.* Septicaemia caused

by *Salmonella dublin* and *Streptococcus pyogenes.* Erysipelas caused by *Erysipelothrix rhusiopathiae.*

5. CONTRAINDICATIONS

Duphacycline LA is not recommended for horses, dogs and cats.

Not for use in animals suffering from renal or hepatic damage or known hypersensitivity.

6. ADVERSE REACTIONS

Duphacycline LA is well tolerated. The occasional reaction which may follow its administration is usually transient.

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

7. TARGET SPECIES

Cattle, pigs and sheep

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

By deep intramuscular injection, 20mg/kg bodyweight.

Cattle, sheep and pigs

5 ml per 50 kg (Not more than 20 ml for cattle, 10 ml for pigs and 5 ml for sheep should be given in any one site)

Piglets	1 day	0.2 ml
	7 days	0.3 ml
	14 days	0.4 ml
	21 days	0.5 ml
	over 21 days	1.0 ml/10kg

9. ADVICE ON CORRECT ADMINISTRATION

Do not dilute.

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken during treatment.

Milk for human consumption may be taken from cows only after 10 days from the last treatment.

Milk for human consumption may be taken from sheep only after 7 days from the last treatment.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 31 days from the last treatment. Pigs may be slaughtered for human consumption only after 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 9 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Following withdrawal of the first dose, use within 28 days. Discard unused material. When the vial has been broached and contents exposed to air, the solution may darken, but the potency will be unchanged.

Do not store above 25ºC. Protect from light.

Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Wash hands after use.

In case of contact with eyes or skin, wash immediately with water as irritation may occur.

If concurrent treatment is administered use a separate injection site.

For animal treatment only

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

Dispose 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

May 2013

15. OTHER INFORMATION

LEGAL CATEGORY

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4039

PACKAGE QUANTITIES

Multidose vials of 100 ml.

FURTHER INFORMATION

Duphacycline LA has been formulated to provide therapeutic levels of oxytetracycline in the blood stream for at least 4 days following a single intramuscular injection. Maximum blood levels are achieved between 4 and 8 hours making the product suitable for the treatment of acute infections. When the container is broached for the first time, using the in-house shelf life which is specified on this package insert, the date in which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Approved: 18/01/2018