ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 glass vial of 20 ml
Box with 1 glass vial of 50 ml
Box with 1 glass or PET vial of 100 ml
Box with 1 glass or PET vial of 250 ml
Box with 10 glass or PET vial of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXTRA DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats
Oxytetracycline (as oxytetracycline hydrochloride)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance: Oxytetracycline (as oxytetracycline hydrochloride) 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

Box with 1 glass vial of 20 ml
Box with 1 glass vial of 50 ml
Box with 1 glass or PET vial of 100 ml
Box with 1 glass or PET vial of 250 ml
Box with 10 glass or PET vial of 100 ml

5. TARGET SPECIES

Cattle, sheep, pigs, horses, dogs and cats.

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular, intravenous, subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period

24-hour dosage regimen

	i.m. use	i.v. use
Cattle:		

Meat and offal	35 days	35 days
Milk	144 hours	144 hours
Sheep:		
Meat and offal	53 days	53 days
Milk	144 hours	144 hours
Pigs:		
Meat and offal	14 days	14 days
Horses:		
Meat and offal	6 month	6 month

Not authorised for use in horses producing milk for human consumption.

Prolonged action dosage regimen

	i.m. use
Cattle:	
Meat and offal	35 days
Sheep:	
Meat and offal	18 days
Pigs:	
Meat and offal	13 days

The prolonged dosage regimen is not authorised for use in animals producing milk for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month /year}

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

11. SPECIAL STORAGE CONDITIONS

Store below 30°C.

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

Disposal: read the package leaflet.

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

Fatro S.p.A.
Via Emilia 285
I-40064 Ozzano Dell'Emilia BO
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4007

17. MANUFACTURER'S BATCH NUMBER

LOT. {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
20 ml label
50 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXTRA DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats
Oxytetracycline (as oxytetracycline hydrochloride)

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains: Oxytetracycline (as oxytetracycline hydrochloride) 100 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular, intravenous, subcutaneous use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period

24-hour dosage regimen

	i.m. use	i.v. use
Cattle:		
Meat and offal	35 days	35 days
Milk	144 hours	144 hours
Sheep:		
Meat and offal	53 days	53 days
Milk	144 hours	144 hours
Pigs:		
Meat and offal	14 days	14 days
Horses:		
Meat and offal	6 month	6 month

Not authorised for use in horses producing milk for human consumption.

Prolonged action dosage regimen

	i.m. use
Cattle:	
Meat and offal	35 days
Sheep:	
Meat and offal	18 days
Pigs:	

Meat and offal 13 days

The prolonged dosage regimen is not authorised for use in animals producing milk for human consumption.

6. BATCH NUMBER

LOT. {number}

7. EXPIRY DATE

EXP{month /year}
Shelf-life after first opening the container: 28 days.
Once opened, use by _____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 ml label
250 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXTRA DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats
Oxytetracycline (as oxytetracycline hydrochloride)

2. STATEMENT OF THE ACTIVE SUBSTANCES

Each ml contains:
Active substance: Oxytetracycline (as oxytetracycline hydrochloride) 100 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, sheep, pigs, horses, dogs and cats.

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular, intravenous, subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period

24-hour dosage regimen

	i.m. use	i.v. use
Cattle:		
Meat and offal	35 days	35 days
Milk	144 hours	144 hours
Sheep:		
Meat and offal	53 days	53 days
Milk	144 hours	144 hours
Pigs:		
Meat and offal	14 days	14 days
Horses:		
Meat and offal	6 month	6 month

Not authorised for use in horses producing milk for human consumption.

Prolonged action dosage regimen

	i.m. use
Cattle:	
Meat and offal	35 days

Sheep:
Meat and offal 18 days
Pigs:
Meat and offal 13 days

The prolonged dosage regimen is not authorised for use in animals producing milk for human consumption.

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 opened, use by _____.

11. SPECIAL STORAGE CONDITIONS

Store below 30°C.

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

Disposal: read package leaflet.

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

Fatro S.p.A.
Via Emilia 285
I-40064 Ozzano Dell'Emilia BO
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4007

17. MANUFACTURER'S BATCH NUMBER

LOT. {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

OXTRA DD
100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats

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

Marketing authorisation holder:
Fatro S.p.A.
Via Emilia 285
I-40064 Ozzano Dell'Emilia BO
Italy

Manufacturer responsible for batch release:
FATRO S.p.A. - Via Emilia, 285 - Ozzano dell'Emilia (Bologna), Italy.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXTRA DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cat
Oxytetracycline (as oxytetracycline hydrochloride)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:
Active substance:

Oxytetracycline (as oxytetracycline hydrochloride)	100 mg

Excipients:

Sodium formaldehyde sulfoxylate	5 mg

Solution for injection.
Clear yellow to brown-yellow solution.

4. INDICATIONS

For the treatment of infections caused by organisms susceptible to oxytetracycline in horses, cattle, sheep, pigs, dogs and cats.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses during concomitant corticosteroid therapy.

6. ADVERSE REACTIONS

Although the product is well tolerated, occasionally a slight local reaction of a transient nature has been observed.
Tetracyclines have also 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.
After intravenous administration of high doses of oxytetracycline in horses, enteritis due to alterations of the intestinal flora can be observed very rarely.
In very rare cases, hypersensitivity (allergic) reactions to treatment may occur, which may require appropriate symptomatic treatment.

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. For details regarding the national system please contact NCA.

7. TARGET SPECIES

Cattle, sheep, pigs, horses, dogs and cats.

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

DD = dual dosage scheme

The product can be administered either every 24 hours at a low dose rate, or at a higher dose rate for prolonged duration of action. To avoid excessive residues at the injection site, maximum injection volumes per injection site are applicable.

Cattle, sheep, pigs, horses: Intramuscular or intravenous use.

Dogs, cats: Subcutaneous or intramuscular use.
24 hourly dosage regimen:
Dose rate: 3 – 10 mg/kg body weight depending on age and species (see table).
The treatment may be repeated at 24 hour intervals for 3 to 5 consecutive days.).

Intravenous injections must be given slowly over a period of at least one minute.

Prolonged action dosage regimen:

Dose rate: 10 or 20 mg/kg body weight depending on age and species (see table).
Route of administration: Intramuscular injection only, repeated once after 48 – 60 hours if required.
This dosage regimen is not recommended for use in horses, dogs or cats or animals producing milk for human consumption.

Treatment and metaphylaxis of enzootic abortion in sheep:
Dose rate: 20 mg/kg body weight administered between day 95 – 100 of gestation.
A further treatment may be given 2 – 3 weeks later.
For metaphylaxis, the presence of the disease in the group must be established before the product is used.

Clean and disinfect the injection site before administration.
Repeat doses should be administered at different sites, and the sites massaged well after injection.

The maximal volume to be administered per injection site is 20 mL for adult cattle and horses, 10 mL for calves and sheep, and 5 ml for pigs. If larger volumes are required, the injection volumes should be divided over different injection sites.

Animal	Body weight (kg)	24 hourly dose		Prolonged action dose	
		Dose (mg/kg)	Volume (ml)	Dose (mg/kg)	Volume (ml)
Horse	500	5	25	Not recommended	
Foal	100	10	10	Not recommended	
Cow	500	3	15	10	50
Calf	100	8	8	20	20
Sow/boar	150	5	7.5	10	15
Pig	25	8	2	20	5
Sheep	50	8	4	20	10
Lamb	25	8	2	20	5
Dog	10	10	1	Not recommended	
Cat	5	10	0.5	Not recommended	

The 20 ml and 50 ml vials should not be broached more than 40 times, the 100 ml and 250 ml vials should not be broached more than 20 times.
The user should select the most appropriate vial size according to the target species to be treated.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.

10. WITHDRAWAL PERIOD(S)

24-hour dosage regimen

	i.m. use	i.v. use
Cattle:		

Meat and offal	35 days	35 days
Milk	144 hours	144 hours
Sheep:		
Meat and offal	53 days	53 days
Milk	144 hours	144 hours
Pigs:		
Meat and offal	14 days	14 days
Horses:		
Meat and offal	6 month	6 month

Not authorised for use in horses producing milk for human consumption.

Prolonged action dosage regimen

	i.m. use
Cattle:	
Meat and offal	35 days
Sheep:	
Meat and offal	18 days
Pigs:	
Meat and offal	13 days

The prolonged dosage regimen is not authorised for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

When the container is broached for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

Special precautions for use
None.

Special precautions for use in animals
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.

The product should be used cautiously in animals with hepatic or renal impairment.
Use with caution in horses with gastro-intestinal disturbances or under stress.
See “Pregnacy and lactation” before use in male animals.
Do not dilute the product.
If concurrent treatment is administered, use a separate injection site.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause sensitisation, skin and eye irritation.
People with known hypersensitivity to tetracyclines, such as oxytetracycline, should avoid contact with the veterinary medicinal product.
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 or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation
Laboratory studies have not produced any evidence of embryotoxic or teratogenic effects. However, use only accordingly to the benefit-risk assessment by the responsible veterinarian.
The product can be safely administered to lactating animals.
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 following risk benefit assessment by the responsible veterinarian.
Oxytetracycline is excreted in milk; concentrations are generally low.
Parenteral use of tetracyclines may alter fertility in the male.

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)
Oxytetracycline has a low toxicity, but is an irritant substance. Overdose should be avoided, particularly in horses.
There is no known specific antidote, if signs of possible overdose occur treat the animal symptomatically.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Environmental properties
Oxytetracycline is very persistent in soil.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

Pack-sizes:
1 x 20 ml glass vial
1 x 50 ml glass vial
1 x 100 ml glass or PET vial
1 x 250 ml glass or PET vial
10 x 100 ml glass or PET vials

Not all pack sizes may be marketed.

Veterinary use. To be supplied only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.

Approved 13 November 2020