PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}

Cardboard box:
1 x 20 ml glass vial
1 x 50 ml glass vial
1 x100 ml glass or PET vial
1 x 250 ml glass or PET vial
10 x 100 ml glass or PET vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance: Oxytetracycline 100 mg (as oxytetracycline hydrochloride)
Excipients: Sodium formaldehyde sulfoxylate 5 mg

3. PACKAGE SIZE

1 x 20 ml glass
1 x 50 ml glass
1 x 100 ml glass or PET
1 x 250 ml glass or PET
10 x 100 ml glass or PET

4. TARGET SPECIES

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

5. INDICATION(S)

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6. ROUTES OF ADMINISTRATION

Cattle, sheep, pigs, horses: Intramuscular or intravenous use.
Dogs, cats: Subcutaneous or intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:

24-hour dosage regimen

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

Milk	72 hours	72 hours
Sheep:		
Meat and offal	53 days	53 days
Milk	120 hours	120 hours
Pigs:		
Meat and offal	14 days	14 days
Horses:		
Meat and offal	6 months	6 months

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached, use by _____

9. SPECIAL STORAGE PRECAUTIONS

Store below 30°C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Fatro S.p.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 11557/5004

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {NATURE/TYPE}

100 ml
250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

Excipients: Sodium formaldehyde sulfoxylate 5 mg

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Cattle, sheep, pigs, horses: Intramuscular or intravenous use.
Dogs, cats: Subcutaneous or intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

24-hour dosage regimen

	i.m. use	i.v. use
Cattle:		
Meat and offal	35 days	35 days
Milk	72 hours	72 hours
Sheep:		
Meat and offal	53 days	53 days
Milk	120 hours	120 hours
Pigs:		
Meat and offal	14 days	14 days
Horses:		
Meat and offal	6 months	6 months

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. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached, use by _____

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

Store below 30°C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Fatro S.p.A.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: read the package leaflet.

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{NATURE/TYPE}
20 ml
50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXTRA DD

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached, use by _____

5. ROUTE(S) OF ADMINISTRATION

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

Dogs, cats: Subcutaneous or intramuscular use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains:
Active substance:
Oxytetracycline 100 mg (as oxytetracycline hydrochloride)
Excipients:
Sodium formaldehyde sulfoxylate 5 mg

Clear yellow to brown-yellow solution.

3. TARGET SPECIES

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

4. INDICATIONS FOR USE

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. SPECIAL WARNINGS

Special precautions for use
None.

Special precautions for use in animals
Use of the veterinary medicinal product should be based on identification and susceptibility testing of target pathogen. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.Use of the veterinary medicinal 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 veterinary medicinal 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 “Fertility” before use in male animals.

Do not dilute the veterinary medicinal 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 veterinary medicinal 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.

Fertility:

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.

7. ADVERSE EVENTS

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

Rare (1 to 10 animals / 10,000 animals treated):	Hepatic toxicosis; Blood dyscrasia.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction [a]; Application site skin change.
Undetermined frequency	Discoloured teeth and bones [b]; Photosensitivity.

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Enteritis[c]

[a]Hypersensitivity (allergic) reactions to treatment may occur, which may require appropriate symptomatic treatment;
[b]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;
[c]After intravenous administration of high doses of oxytetracycline due to alterations of the intestinal flora.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine e-mail: adverse.events@vmd.gov.uk

8. DOSAGE FOR EACH SPECIES, ROUTES 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 PERIODS

Withdrawal period:

24-hour dosage regimen

	i.m. use	i.v. use
Cattle:		
Meat and offal	35 days	35 days
Milk	72 hours	72 hours

Sheep:		
Meat and offal	53 days	53 days
Milk	120 hours	120 hours
Pigs:		
Meat and offal	14 days	14 days
Horses:		
Meat and offal	6 months	6 months

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 immediate packaging: 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 PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 11557/5004

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

FATRO S.p.A.
Via Emilia, 285
40064 Ozzano dell'Emilia (Bologna), Italy.

Local representatives and contact details to report suspected adverse reactions:

DUGV (UK) Ltd.
Union House
111 New Union Street
Coventry, CV1 2NT
Phone: +353 (0) 504 43169

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

17. OTHER INFORMATION

Environmental properties
Oxytetracycline is very persistent in soil.

Veterinary use. Veterinary medicinal product subject to prescription.
Administration by a veterinary surgeon or under their direct responsibility.

Gavin Hall

Approved: 13 August 2024