1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxtra DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats (BE, DE, DK, EL, IE, NL, PL, PT, RO, UK(NI))

Oxtra vet 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats (NO, SE)

Oxtra 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats (AT)

Bimodula 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats (ES, IT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Povidone K12	
Ethanolamine	
Magnesium oxide light	
Sodium formaldehyde sulfoxylate	5 mg
Hydrochloric acid (10% diluted)	
Water for injections	

Clear yellow to brown-yellow solution with no visible particles.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 3.7 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 veterinary medicinal 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 veterinary medicinal 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 accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 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):	Enteritis[a] Hypersensitivity reaction[b]
Undetermined frequency (cannot be estimated from the available data):	Injection site reaction[c] Dental and bone discolouration [d] Photosensitivity Delayed healing or bone growth[e]

[a] In horses alterations to intestinal flora can occur after high dose intravenous administrations.
[b] May require appropriate symptomatic treatment.
[c] Slight and transient.
[d] Can cause a yellow, brown or grey discolouration of bones and teeth in young animals.
[e] At high dose or following chronic administration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 veterinary medicinal 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.

3.8 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.

3.9 Administration routes and dosage

<DD: dual dosage scheme.>

The veterinary medicinal 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.

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

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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01AA06

4.2 Pharmacodynamics

Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis.
Oxytetracycline is a bacteriostatic antibiotic which has broad spectrum antibacterial activity against both Gram-positive and Gram-negative bacteria.
Multiple genes have been identified which mediate resistance to tetracyclines and these genes may be carried on plasmids or transposons between both pathogenic and non-pathogenic bacteria. The most common mechanisms of resistance involve either the removal of the antibiotic from the organism by energy dependent efflux pumps or protection of the ribosome from binding by altered target sites. Resistance to one tetracycline confers cross-resistance across the whole group.

In vitro, oxytetracycline is active against a range of both Gram-positive and Gram-negative microorganisms including: *Streptococcus* spp., *Staphylococcus* spp., *Listeria monocytogenes*, *Mannheimia haemolytica*, *Haemophilus parahaemolyticus* and *Bordetella bronchiseptica*, and against *Chlamydophila abortus*, the causative organism of enzootic abortion in sheep.
The MIC of Oxytetracycline against some of the target bacteria are reported in the following table (source: VetPath 2015-2016, CLSI 2017-2018; ComPath 2013-2014, CLSI 2013-2015):

Species	**Pathogen (number of isolates)**	**MIC 50 *µg/ml***	**MIC 90 *µg/ml***	**Resistance % (CLSI breakpoints *µg/ml*)**
Cattle	*Pasteurella multocida* (155)	0.5	8	11.6 (≥8)
	Mannheimia haemolitica (91)	0.5	16	17.6 (≥8)
Horses	*Streptococcus zooepidemicus (164)*	-	-	<74
	Streptococcus equi (26)	-	-	<20
	Actinobacillus equuli (28)	-	-	<14
	Staphilococccus aureus (70)	-	-	<34
Pigs	*Pasteurella multocida* (171)	0.5	2	10.5 (≥2)
	Actinobacilus pleuropneumoniae (164)	0.5	16	21.3 (≥2)
	Streptococcus suis 131)	32	64	82.4 (≥2)
Dogs	*Staphilococccus intermedius* (80)	0.25	>8	45.0 (≥16)
	Staphilococccus aureus (23)	0.5	>8	13.0 (≥16)
	Streptococcus spp (35)	2	>8	40.0 (≥8)

Species	Pathogen (number of isolates)	MIC 50 *µg/ml*	MIC 90 *µg/ml*	Resistance % (CLSI breakpoints *µg/ml*)
	Bordetella bronchiseptica (25)	1	>8	-
	E. coli (33)	4	>8	18.2 (≥16)
	Pasteurella multocida (14)	0.5	0.5	-
	Pseudomonas aeruginosa (23)	>8	>8	-
Cats	*Streptococcus spp* (23)	4	>8	21.7 (≥8)
	Staphilococccus intermedius (15)	0.25	>8	46.7 (≥16)
	Staphilococccus aureus (16)	0.5	>8	12.5 (≥16)
	CNS (35)	0.5	>8	11.4 (≥16)
	Pasteurella multocida (84)	0.5	0.5	-
	Bordetella bronchiseptica (13)	1	1	-
	Pseudomonas aeruginosa (23)	>8	>8	-
	E. coli (22)	4	>8	13.6 (≥16)

- = not available.

4.3 Pharmacokinetics

Oxytetracycline is widely distributed in the body with the exception of CSF and it binds to plasma proteins in a variable manner depending on the species (20-40%).
Oxytetracycline is excreted mainly unchanged via the renal route, some in faeces and milk. It is also excreted by the bile but a high proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

4.4 Environmental properties

Oxytetracycline is very persistent in soil.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store below 30 °C.

5.4 Nature and composition of immediate packaging

20 ml, 50 ml, 100 ml, 250 ml amber type II glass vials and 100 ml, 250 ml amber PET vials, closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.

Pack-sizes:
Cardboard box with 1 glass vial of 20 ml
Cardboard box with 1 glass vial of 50 ml
Cardboard box with 1 glass or PET vial of 100 ml
Cardboard box with 1 glass or PET vial of 250 ml
Cardboard box with 10 glass or PET vials of 100 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box:
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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxtra DD 100 mg/ml solution for injection (BE, DE, DK, EL, IE, NL, PL, PT, RO, UK(NI)).
Oxtra vet 100 mg/ml solution for injection (NO, SE).
Oxtra 100 mg/ml solution for injection (AT).
Bimodula 100 mg/ml solution for injection (ES, IT).

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains Oxytetracycline 100 mg (as oxytetracycline hydrochloride)

3. PACKAGE SIZE

1 x 20 ml
1 x 50 ml
1 x 100 ml
1 x 250 ml
10 x 100 ml

4. TARGET SPECIES

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

5. INDICATIONS

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 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.

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

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 ml glass or PET vial
250 ml glass or PET vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxtra DD 100 mg/ml solution for injection (BE, DE, DK, EL, IE, NL, PL, PT, RO, UK(NI)).
Oxtra vet 100 mg/ml solution for injection (NO, SE).
Oxtra 100 mg/ml solution for injection (AT).
Bimodula 100 mg/ml solution for injection (ES, IT).

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains Oxytetracycline 100 mg (as oxytetracycline hydrochloride)

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.

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 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. EXPIRY DATE

Exp. {mm/yyyy}

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

7. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml glass vial
50 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxtra DD (BE, DE, DK, EL, IE, NL, PL, PT, RO, UK(NI))
Oxtra vet (NO, SE)
Oxtra (AT)
Bimodula (ES, IT)

2. 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 _____

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Oxtra DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats (BE, DE, DK, EL, IE, NL, PL, PT, RO, UK(NI)).
Oxtra vet 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats (NO, SE).
Oxtra 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats (AT).
Bimodula 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats (ES, IT).

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 with no visible particles.

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 safe use in the target species:
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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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:
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.

Major 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):	Enteritis[a] Hypersensitivity reaction[b]
Undetermined frequency (cannot be estimated from the available data):	Injection site reaction[c] Dental and bone discolouration [d] Photosensitivity Delayed healing or bone growth[e]

[a] In horses alterations to intestinal flora can occur after high dose intravenous administrations.
[b] May require appropriate symptomatic treatment.
[c] Slight and transient.
[d] Can cause a yellow, brown or grey discolouration of bones and teeth in young animals.
[e] At high dose or following chronic administration.

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: {national system details}.

8. Dosage for each species, routes and method of administration

DD = dual dosage scheme

The veterinary medicinal 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 veterinary medicinal 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

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 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 after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 or pharmacist 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

Cardboard box with 1 x 20 ml glass vial
Cardboard box with 1 x 50 ml glass vial
Cardboard box with 1 x 100 ml glass or PET vial
Cardboard box with 1 x 250 ml glass or PET vial
Cardboard box with 10 x 100 ml glass or PET vials

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

FATRO S.p.A.
Via Emilia, 285
40064 Ozzano dell'Emilia (Bologna), Italy.
Tel: +39 051 6512711

Local representatives and contact details to report suspected adverse reactions:

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.