ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXTRA LONG ACTING, 200 mg/ml, solution for injection for cattle, buffalo sheep and goats, swine, broiler chickens, turkeys.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

oxytetracycline hydrochloride	216	mg
equivalent to oxytetracycline	200	mg

Excipients:

sodium formaldehyde sulfoxylate	5	mg
disodium edetate	0.5	mg
other excipients and water for injections q.s. to	1	ml

For a complete list of the excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear reddish-yellow solution

4. CLINICAL INFORMATION

4.1. Target species

Cattle, buffalo, sheep and goats, swine, broiler chickens, turkeys.

4.2. Indications for use, specifying the target species

OXTRA LONG ACTING is indicated in therapy of all infections caused by microorganisms sensitive to oxytetracycline,more specifically: Gram-positive bacteria (amongst which *Arcanobacterium pyogenes*, *Bacillus anthracis*, *Clostridium* spp., *Corynebacterium* spp., *Staphylococcus* spp., *Streptococcus* spp.), Gram-negative bacteria (amongst which *Aerobacter aerogenes*, *Avibacterium* spp., *Bacteroides* spp., *Bordetella* spp., *Brucella* spp., *Dichelobacter nodosus*, *E. coli*, *Fusobacterium necrophorum*, *Haemophilus* spp., *Klebsiella* spp., *Ornithobacterium rhinotracheale*, *Pasteurella* spp., *Proteus* spp., *Pseudomonas* spp., *Salmonella* spp., *Shigella* spp.), Spirochetes, Rickettsiae, Chlamydiae, Mycoplasmas, Actinomycetes, Leptospires and certain Protozoans such as *Anaplasma* spp. and *Toxoplasma* spp.
More specifically:

- bronchopulmonary infections (bronchitis, bronchopneumonia, pleurisy);
- gastrointestinal infections (gastritis, enteritis, calf diphtheria);
- udder infections (septic mastitis, acute parenchymatous mastitis);
- urinary infections (pyelonephritis, septic disorders of the urinary system);
- foot infections (infectious polyarthritis, necrotic-gangrenous foot infections, such as footrot in cattle and sheep);
- metritis, metroperitonitis, puerperal sepsis;
- phlegmon, septic wounds, purulent lesions, treatment of post-traumatic and pre- or post-surgical wounds.

4.3. Contraindications

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not use if resistance to the tetracyclines has been found in the breeding establishment, owing to potential cross-resistance.

Do not administer in cases of ascertained renal insufficiency, as an accumulation of oxytetracycline can occur in the blood, owing to insufficient excretion of the product.

4.4. Special warnings for each target species

In swine below 10 kg in weight, for which the dosage is 1 ml/animal, subcutaneous injection in the retroauricular region is recommended, in order to reduce pain and any local irritation. Intramuscular injection in the thigh must be absolutely avoided.

Use of the product (oxytetracycline) in poultry must comply with Commission Regulation EC 1177/2006 and national implementation regulations.

4.5. Special precautions for use

Special precautions for use in animals

Use of the veterinary medicinal product must be limited to rearing establishments in which the disease has been diagnosed.
Use of the product should be based on sensitivity testing against bacteria isolated from the animals. If this should not be possible, therapy should be based on local epidemiological information (regional or from breeding establishments).
Use of the product other than in the instructions supplied may lead to an increase in the incidence of resistant bacteria and reduce the

efficacy of treatments with other antibacterial agents, owing to the possible appearance of cross-resistance.
In animals affected by renal pathologies, an accumulation of oxytetracycline in the blood may occur, owing to insufficient excretion of the product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Persons with known hypersensitivity to the active substances or to any of the excipients must avoid contact with the veterinary medicinal product.

Care must be taken during administration of the product to avoid accidental self-injection.

In case of accidental self-injection, see a doctor immediately and show the package leaflet or the label.

4.6. Adverse reactions (frequency and seriousness)

The high concentration of the active substance and the prolonged action over time may give rise to transitory local irritation reactions, with edema, swelling and erythema, lasting approximately 5 days.

In hypersensitive animals, photosensitivity, allergic or anaphylactic phenomena can occur, characterised by agitation, horripilation, muscle tremors, diffuse reddening, laboured breathing, sialorrhea and prostration. At the appearance of these symptoms, suitable antidotes must be administered (epinephrine, adrenaline, cortisones, antihistamines, Ca++ ions, etc.).

4.7. Use during pregnancy and lactation

It may be used during pregnancy and lactation.

4.8. Interaction with other medicinal products and other forms of interaction

Combination with penicillin or beta-lactams generally must be avoided, because interference may occur between the bacteriostatic action of oxytetracycline and the bactericidal action of penicillin.
Avoid concurrent administration of OXTRA LONG ACTING and preparations based on iron dextran.
It is recommended that a time interval of 1-2 hours be observed before administration of other products containing polyvalent cations, as these could limit absorption of the tetracyclines.

4.9. Amounts to be administered and administration route

In cattle, buffalo, sheep, goats, swine of a weight greater than 10 kg, broiler chickens and turkeys, OXTRA LONG ACTING should be administered by the deep intramuscular route in a single administration.
In swine of a weight less than 10 kg, subcutaneous injection in the retroauricular region is recommended.

The indicated dosage is the following:

Cattle, buffalo, sheep and goats: 0.15 ml/kg b.w. equivalent to 30 mg/kg b.w. of oxytetracycline;

Swine

- of a weight greater than 10 kg: 0.1 ml/kg b.w. equivalent to 20 mg/kg b.w. of oxytetracycline;
- of a weight below 10 kg: 1 ml/animal, equivalent to 200 mg/animal of oxytetracycline;

Broiler chickens and turkeys: 0.15-0.30 ml/kg b.w. equivalent to 30-60 mg/kg b.w. of oxytetracycline.

It is advisable to repeat the treatment 3 days later, in case of severe infections.
To ensure the correct dosage, the body weight of the animal should be determined as accurately as possible in order to avoid underdosing.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms due to overdose are known.

4.11. Withdrawal periods

Meats and offal
Cattle, buffalo and goats: 39 days
Sheep: 26 days
Swine: 16 days
Broiler chickens: 20 days
Turkeys: 30 days

Milk
Cattle and buffalo: 14 days (28 milkings)
Sheep and goats: 15 days (30 milkings)

Use is not permitted in layer hens and turkeys producing eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterial agents for systemic use, tetracyclines.
ATC Vet code: QJ01AA06.

5.1. Pharmacodynamic properties

OXTRA LONG ACTING is a solution for injection based on oxytetracycline, a bacteriostatic antibiotic which acts by inhibiting bacterial protein synthesis, binding irreversibly with ribosomal subunit 30s. It shows a very broad spectrum of action, which includes Gram-positive bacteria (amongst which *Arcanobacterium pyogenes*, *Bacillus anthracis*, *Clostridium* spp., *Corynebacterium* spp., *Staphylococcus* spp., *Streptococcus* spp.), Gram-negative bacteria (amongst which *Aerobacter aerogenes*, *Avibacterium* spp., *Bacteroides* spp., *Bordetella* spp., *Brucella* spp., *Dichelobacter nodosus*, *E. coli*, *Fusobacterium necrophorum*, *Haemophilus* spp., *Klebsiella* spp., *Ornithobacterium rhinotracheale*, *Pasteurella* spp., *Proteus* spp., *Pseudomonas* spp., *Salmonella* spp., *Shigella* spp.), Spirochetes, Rickettsiae, Chlamydiae, Mycoplasmas, Actinomycetes, Leptospires and certain Protozoans such as *Anaplasma* spp. and *Toxoplasma* spp

5.2. Pharmacokinetic particulars

Oxytetracycline, administered by the parenteral route, is rapidly absorbed and distributes to all tissues, rapidly reaching efficacious therapeutic levels. With a single administration of OXTRA LONG ACTING blood levels are obtained which are sufficient to maintain an efficacious therapeutic protection for 3 days. Oxytetracycline is eliminated with the urine in partially active form.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium formaldehyde sulfoxylate
Disodium edetate
Pyrrolidone
Povidone (E1201)
Heavy magnesium oxide (E530)
Monoethanolamine
Water for injections

6.2. Incompatibilities

Do not mix with other veterinary medicinal products.

6.3. 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.

6.4. Special precautions for storage

Store protected from light and sources of heat.

6.5. Nature and composition of immediate packaging

50, 100, 250 and 500 ml yellow type II glass bottles, with an elastomer closure and aluminium collar, in a cardboard box.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia - Bologna - Italy

8. MARKETING AUTHORISATION NUMBERS

10573

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22/5/1986
Date of renewal: 30/7/2012

10. DATE OF REVISION OF THE TEXT

30/7/2012