

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxipra 20 L.A. Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Oxytetracycline (as oxytetracycline dihydrate) 200 mg

Excipients

Sodium Formaldehyde Sulfoxylate 10 mg

N,N-Dimethylacetamide 467 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and swine.

4.2 Indications for use, specifying the target species

Indicated for the treatment of infections caused by sensitive germs in cattle, sheep and swine: anaplasmosis, respiratory infection, keratoconjunctivitis and metritis, mastitis and aglactia (MMA) syndrome.

4.3 Contraindications

- Do not use in animals which are sensitive to tetracyclines.
- Do not use in animals which have liver or kidney disorders.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not administer more than 10 ml at the injection site.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Intramuscular injection may be painful, producing swelling at the injection site.
In sensitive animals anaphylaxis-like reactions can be observed.

4.7 Use during pregnancy, lactation or lay

The product can be used during these periods.

4.8 Interaction with other medicinal products and other forms of interaction

The product should not be administered together with bactericide antibiotics.

4.9 Amounts to be administered and administration route

For intramuscular injection only.

Cattle and sheep:

20 mg/kg body weight (equivalent to 1 ml of OXIPRA-20 L.A. per 10 kg body weight) in a single dose.

Pigs:

20 mg/kg body weight (equivalent to 1 ml of OXIPRA-20 L.A. per 10 kg body weight) in a single dose.

If necessary, a second dose can be given after 36 hours.

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

Tetracyclines are considered to be of a low order of toxicity, with the predominant effect of administering an overdose to healthy animals being a disruption to gastrointestinal function.

If animals have previous renal disorders, overdose of oxytetracycline can produce severe hepatorenal disturbances.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment or for 22 days thereafter.

Milk withdrawal in cows: 3 days (6 milkings). Milk may not be taken from treated cows for human consumption until 84 hours after the last treatment.

Milk withdrawal in ewes: 3 ½ days (7 milkings). Milk from treated ewes may not be taken for human consumption until 96 hours after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Tetracyclines are bacteriostatic antibiotics which inhibit the synthesis of bacterial proteins. This antibacterial action is the result of the fixation to the ribosomal subunit 30 S by quelant bindings with phosphate groups in RNAm. They inhibit, therefore, the RNAt fixation over the RNAm (codon anticodon interaction).

The spectrum of action of oxytetracycline:

* Gram (+) and Gram (-) bacteria:

- sensitive:

(+): *Streptococcus* and *Clostridium*

(-): *Brucella*, *Haemophilus* and *Klebsiella*

- mild sensitive:

(+): *Corynebacterium* and *Bacillus anthracis*

(-): *E. coli*, *Pasteurella*, *Salmonella*

- resistant:

(+): *Proteus*, *Staphylococcus*

(-): *Pseudomonas*, *Aerobacter aerogenes*, *Shigella* and *Staphylococcus*

Resistance develops slowly being crossed with other tetracyclines.

The conventional Oxytetracycline Injectable preparations produce significant concentrations in the blood for approximately 24 hours after administration. The long action preparations produce significant concentrations in blood and tissues for up to 5 days.

After the intramuscular inoculation of an Oxytetracycline L.A. (long action) preparation a quick, but limited, increase of the Oxytetracycline concentration in serum is observed. The maximum blood concentration (about 4 µg/ml) is achieved at 60-90 minutes post-administration, and it is maintained during 12 hours approximately. Then, the blood concentration starts to decrease having a half-life of more than 20 hours. Oxytetracycline may be detected in serum of animals even 144 hours after administration.

Tetracyclines bind reversibly to the plasma proteins (up to 25% of oxytetracycline may be bound to plasma proteins) and they are widely spread through the whole organism, and concentrate most in the kidneys, liver, spleen and lungs as well as in the active zones of ossification. Also, minor concentrations are found in saliva, ocular humours and milk; it also crosses the placental barrier.

It is difficult for tetracyclines to spread to the cerebrospinal fluid, unless the meninges are swollen.

Tetracyclines are excreted mainly by urine and faeces. Renal excretion takes place through glomerular filtration and the highest concentrations are found in the urine 2-8 hours after administration. Faecal excretion can be up to 10 % of the dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Chloride
Sodium formaldehyde sulfoxylate
Monoethanolamine
N,N - Dimethylacetamide
Water for Injections

6.2 Incompatibilities

Oxytetracycline is not compatible with calcium salts.

6.3 Shelf-life

The product has a validity period of 2 years from the date of manufacture.

Once opened, the vials should not be used after 90 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Clear yellow to pale brown solution filled in amber glass vials of 10 ml (Type I) and amber glass vials of 50ml and 100ml capacity (Type II) closed with an elastomer closure and anodised aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10846/007/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th March 1996

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10 DATE OF REVISION OF THE TEXT

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