1.3 Product information

1.3.1 Summary of product characteristics

1 Name of the veterinary medicinal product

Oxytetracycline 5% injection

2 Qualitative and quantitative composition

Each 1 ml contains 50 mg of Oxytetracycline (as dihydrate), for the full list of excipients, see section 6.1.

3 Pharmaceutical form

Solution for injection.

It is a yellow to red brown clear liquid.

4. Clinical particulars

4.1 Target species

Cattle, sheep and goats

4.2 Indications for use, specifying the target species

Arthritis, gastrointestinal and respiratory infections caused by Oxytetracycline sensitive micro-organisms, like Bordetella, Campylobacter, Chlamydia, E. coli, Haemophilus, Mycoplasma, Psateurella, Rickettsia, Salmonella, Staphylococcus and Streptococcus spp., in calves, cattle, goats, sheep and swine.

4.3 Contraindications

Hypersensitivity to tetracyclines.

Administration to animals with a seriously impaired renal and/or liver function.

Concurrent administration of penicillines, cephalosporines, quinolones and cycloserine.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

If concurrent treatment is administered, use a separate injection site.

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.

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

Take care to avoid accidental injection.

Wash hands after use. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.

4.6 Adverse reactions (frequency and seriousness)

After intramuscular administration local reactions can occur, which disappear in a few days.

Discoloration of teeth in young animals.

Hypersensitivity reactions.

4.7 Use during pregnancy, lactation or lay

Oxytetracycline can retard skeletal growth of the fetus if administered during pregnancy.

The use of tetracyclines during the period of tooth development, including late pregnancy, may lead to tooth discolouration.

Tetracyclines are excreted in milk.

The product should only be used according to the benefit/risk assessment by the responsible veterinary surgeon.

4.8 Interaction with other medicinal products and other forms of interaction

Do not dilute or mix with other compounds.

4.9 Amounts to be administered and administration route

For intramuscular or subcutaneous administration:

Full-grown animals: 1ml per 5-10kg body weight, for 3-5days.

Young animals: 2ml per 5-10kg body weight, for 3-5days.

Do not administer more than 10ml in swine and more than 5ml in calves, goats and sheep per injection site.

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

There is no known specific antidote.

If signs of possible overdose occur, treat the animal symptomatically.

4.11 Withdrawal period(s)

-For meat: 12 days.

-For milk: 5 days.

5 Pharmaceutical properties

5.1 Pharmacodynamic properties

Oxytetracycline is active against a wide range of Gram positive and Gram negative pathogenic bacteria, and certain Rickettsia. 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 amino-acyl transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

5.2 Pharmacokinetic particulars

Oxytetracycline is widely distributed in the body, including to the kidneys, liver, lungs and muscle, though only small quantities are distributed to the CSF. The placenta is readily passed by oxytetracycline and concentration in the fetal blood may reach that of the maternal circulation. Oxytetracycline apparently is not metabolised in vivo and is eliminated primarily unchanged, via glomerular filtration. It is also excreted into the GI tract via both biliary and non-biliary routes and may become inactive after chelation with faecal material.

6. Pharmaceutical particulars

6.1 List of excipients

Magnesium oxide

N-Mehtylpyrrolidone

Water for injection

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed 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: 30 days.

6.4. Special precautions for storage

Store at the temperature below 30℃ and protect from light.

6.5 Nature and composition of immediate packaging

Brown glass vials 100ml, with rubber stoppers, sealed with aluminum caps.

6.6 Special precautions for the disposal of unused veterinary medicinal product

or waste materials derived from the use of such products, if appropriate

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

1.3.2 Labeling

1.3.3 Package insert

1.4 Regional summaries

1.4.1 Bioequivalence trial information form (BTIF)

See next page.