Summary of product characteristics

1.Name of the veterinary medicinal product

TENALINE 20% VETERINARY

2.Qualitative and quantitative composition

1 ml contains :
Active substances :
Oxytetracycline ..... 200.0 mg
(As dihydrate) (equivaelent to 215,6 mg of dehydrated oxytetracyclin)
Excipients :
Sodium hydroxymethanesulphinate ....1.5 mg

For a full list of excipients, see section “List of excipients”.

3.Pharmaceutical form

Injectable solution.
Clear solution, yellow to brown-orange

4.Clinical particulars

4.1. Target species

Cattle and Sheep.

4.2. Indications for use, specifying the target species

Cattle and Sheep :
-
Cattle:
Treatment of infections caused by microorganisms sensitive to oxytetracycline.
Sheep:
Treatment and control of abscesses enzootic abortion foot rot joint and navel III mastitis metritis peritonitis pneumonia post operative post partum and wound infections.

4.3. Contra-indications

Do not use in case of hypersensitivity to oxytetracycline or any other substance of tetracycline group.
Do not use in case of known resistance to tetracyclines.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

i) Special precautions for use in animal
None.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not handle in case of known hypersensitivity to tetracyclines.
In case of reaction after exposure to the product (skin rash for example), consult a doctor.

iii) Other precautions
None.

4.6. Adverse reactions (frequency and seriousness)

Locally, intolerance reactions can be observed from a pain at injection site or muscular necrosis lesions.
As for all the tetracyclines, general adverse effects have been noted such as gastrointestinal disorders, less frequently some allergic reactions and photosensibility.
Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il/

4.7. Use during pregnancy and lactation

Oxytetracycline showed no sign of embryotoxicity or teratogenicity in laboratory animals. In mammals, oxytetracycline crosses the placenta, causing discoloration of teeth and slow growth fetus.
Tetracyclines are found in breast milk. Safety of the product has not been evaluated in pregnant or lactating.
Use of the product in pregnant or lactating should be based on the benefit/risk assessment done by the responsible veterinarian.

4.8. Interaction with other medicaments and other forms of interaction
Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines.

4.9. Amounts to be administered and administration route
Intramuscular route for cattle and ovine.

20 mg oxytetracycline/kg bw in a single injection, i.e. 1 ml of injectable solution per 10 kg body weight.

If clinical signs of disease persist 72 hours after the first dose, a second administration of 20 mg oxytetracycline per kg can be performed.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary
See section "Adverse reactions".

4.11. Withdrawal period
Cattle: Meat 28 days, Milk 8 days
Sheep: Meat 16 days

5.Pharmacological properties

Pharmacotherapeutic group: antibiotics, tetracyclines.
ATCvet code: QJ01AA06.

5.1.Pharmacodynamic properties
Oxytetracycline reversibly binds to the 30S ribosomal fraction receptors, leading to blocking of the aminoacyl-tRNA binding at the corresponding site of the ribosome-messenger RNA

complex. This results in an inhibition of the protein synthesis and thus a stop of the growth of the bacterial culture. Oxytetracycline has a mainly bacteriostatic activity.

The bacteriostatic activity of oxytetracycline involves penetration of the substance into the bacterial cell. The penetration of oxytetracycline is exerted by both passive and active diffusion. The main mode of possible resistance is related to the possible presence of a R factor responsible for a decrease in the active transport of oxytetracycline.

Oxytetracycline is a broad-spectrum antibiotic. It is primarily active against gram-positive and negative microorganisms, aerobic and anaerobic, as well as against mycoplasma, chlamydia and Rickettsiae.

Acquired resistance to oxytetracycline has been reported. Such resistance is usually of plasmid origin. Cross resistance to other tetracyclines is possible. Continuous treatment with low doses of oxytetracycline may also result in increased resistance to other antibiotics.

5.2. Pharmacokinetic particulars

After administration, oxytetracycline is rapidly absorbed and distributed throughout the body, with the highest concentrations found in the kidneys, liver, spleen and lungs. Oxytetracycline crosses the placental barrier.
The excipients of the specialty and the form of oxytetracycline used ensure a concentration of oxytetracycline in the plasma greater than 0.5 µg / ml for about 72 hours, following an intramuscular injection at the dose of 20 mg / kg.

Oxytetracycline binds to plasma proteins in a variable manner depending on the species (20-40%).

Oxytetracycline is eliminated as unchanged form, mainly by the urinary tract. It is also excreted by the bile duct but a large proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

6. Pharmaceutical particulars

6.1. List of excipients

Sodium hydroxymethanesulfinate, Oxyde heavy magnesium (E530), Dimethylacetamide, Monoethanolamine, Water for injection.

6.2. Major incompatibilities

None known.

6.3. Shelf life

3 years. Period after opening : 28 days.

6.4. Special precautions for storage

Store below 25°C.Protect from light.

6.5. Nature and composition of immediate packaging

Type II coloured glass vials
Coloured polypropylene / ethylene vinyl alcohol (EVOH)/ polypropylene vials
Chlorobutyl stoppers
Aluminium and plastic flip capsule.

6.6.Special precautions for the disposal of the unused product or waste materials if any

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. Marketing authorization holder
MIP VETERINARIA LTD
POB 10437 HAIFA BAY, 26113, ISRAEL

Manufacturer
CEVA SANTE ANIMALE
10 AVENUE DE LA BALLASTIERE
33500 LIBOURNE

8. Marketing authorization numbers
082-01-92223-00Box of 1 vial of 50 ml.
Box of 1 vial of 100 ml.
Box of 1 vial of 250 ml.
Box of 1 vial of 500 ml.
Not all pack sizes may be marketed.

9. Date of first authorisation/renewal of the authorisation
09/03/2015

10. Date of revision of the text
Revised in 11/06/2021 according to MOHs guidelines