[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXYGAN 500 mg/g POWDER FOR USE IN DRINKING WATER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
Oxytetracycline (hydrochloride) ..... 500 mg

Excipient:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for use in drinking water
Yellow powder

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calf), sheep (lamb), goats (kid), pigs, rabbits, broiler, layer hen, turkeys and duck.

4.2 Indications for use, specifying the target species

Treatment and metaphylaxis of septicemia, respiratory infections and digestive infections due to oxytetracycline-sensitive organisms.
The presence of the disease in the group/flock must be established before the product is used.

4.3 Contraindications

Do not use in case of known hypersensitivity to oxytetracycline, any other tetracycline or any excipient.
Do not use in case of known resistance to tetracyclines.
Do not use in animals with a functional rumen.
Do not use in animals with hepatic or renal alterations.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

Whenever possible, the antimicrobial should only be used based on susceptibility testing. Official and local antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the oxytetracyclines and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross resistance.

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

Tetracyclines may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
This product may cause irritation of the respiratory airways. Avoid inhaling dust when handling the product. Use in a well-ventilated area away from draughts. A dust mask (either a disposal half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143) should be worn when handling the veterinary medicinal product.
This product may cause skin and ocular irritation. Avoid contact with skin and eyes. Personal protective equipment consisting of gloves, goggles and suitable protective clothing should be worn when handling the veterinary medicinal product.
In case of accidental eye or skin contact, rinse the affected area with large amounts of clean water. If irritation occurs, seek medical advice immediately and show the label to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.
Do not smoke, eat or drink while handling the product.

4.6 Adverse reactions (frequency and seriousness)

Gastrointestinal disturbances may occur rarely.
Hypersensitivity and photosensitivity reactions may occur very rarely.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in animals have not produced any evidence of embryotoxicity or teratogenic effects.In mammals, oxytetracycline passes the placental barrier, resulting in staining of teeth and slow foetal growth.
Tetracyclines are found in breast milk.
Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines. Tetracylines should not be administered with antacids, aluminum-based gels, vitamin or mineral preparations as insoluble complexes are formed, which decreases the absorption of the antibiotic.
Oxytetracycline may interfere with the action of bactericidal antimicrobials, such as penicillins and cephalosporins, and therefore they should not be used simultaneously.

4.9 Amounts to be administered and administration route

For administration in drinking water.

20 mg of oxytetracycline / kg body weight per day for 3 to 5 days in the drinking water, equivalent to 400 mg of oral powder per 10 kg body weight per day.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

The amount of medicinal drinking water consumed by animals depends on their physiological and clinical status. In order to obtain the recommended dosage, the oxytetracycline concentration should be adjusted accordingly.

For the preparation of medicated water the body weight of the animals to be treated and their actual daily water consumption should be taken into account. Consumption may vary depending on factors like species, age, state of health, breed and husbandry system (e.g. different temperature, different light regimes). In order to obtain the correct dosage the concentration of oxytetracycline has to be adjusted accordingly.

The following formula may be used to calculate the required amount of veterinary medicinal product in mg per litre of drinking water:

$$\frac{\textbf{x}\text{ mg product per kg bodyweight per day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (L) per animal}} = \textbf{x}\text{ mg product per litre drinking water}$$

The maximum solubility of the product is 65 g/L at 5ºC (15 min).

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

4.11 Withdrawal period(s)

Meat and offal:
Calves, lambs, kids, pigs, laying hens, turkeys and ducks: 7 days
Broiler chickens: 3 days
Rabbits: 1 day.

Eggs: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives for systemic use. Tetraciclines. Oxytetracycline.
ATC vet code: QJ01AA06

5.1 Pharmacodynamic properties
Oxytetracycline is a time-dependent antimicrobial that binds reversibly to the 30 S ribosomal subunit, resulting in a blockade of the aminoacyl-tRNA binding to the corresponding site of the ribosome-mRNA complex. This leads to the inhibition of protein synthesis and, therefore, stops the growth of the bacterial culture.

The bacteriostatic activity of oxytetracycline implies the penetration of the substance into the bacterial cell, this occurs both by active and passive diffusion.

Oxytetracycline is a broad-spectrum antibiotic active against Gram positive and negative bacteria, aerobic and anaerobic, and against mycoplasma, Chlamydia and Rickettsia.
The main mechanism of resistance is related to the presence of an R factor responsible for a reduction of the active transport of oxytetracycline.
The resistances presented are usually of plasmid origin. Cross resistance to other tetracyclines is possible. Continuous treatment at low doses of oxytetracyclines can also produce an increase in resistance to other antibiotics.

5.2 Pharmacokinetic particulars

The absorption of oxytetracycline orally in fasted animals is 2-4 hours and its bioavailability is 60-80%.
The bioavailability can be reduced with the presence of food in the stomach making the oxytetracycline insoluble by chelating with divalent and trivalent cations.
In pigs, the influence of food on the bioavailability of oxytetracycline is less than 5%.

Oxytetracycline binds to plasma proteins in a variable manner depending on the species (20-40%). Its distribution is wide because it diffuses throughout the body, the highest concentrations are found in the kidneys, liver, spleen and lungs. Oxytetracycline crosses the placental barrier.

Oxytetracycline is excreted unaltered mainly through the kidneys. It is also excreted in bile, but a large proportion of oxytetracycline is reabsorbed in the small intestine (enterohepatic circulation).

5.3 Environmental properties

Oxytetracycline is persistent in soil.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary 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: 7 days
Shelf life after dilution in drinking water according to directions: 24 hours

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is packed in thermo-sealed polyethylene / aluminium / polypropylene bags of 1 kg and 100 g.

Package size:
Bag of 1 kg
Bag of 100 g

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

s.p. veterinaria, s. a.
Ctra. Reus – Vinyols, Km. 4,1
Apartado de correos nº 60 – 43330 RIUDOMS (Tarragona)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

DD/MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE