B. PACKAGE LEAFLET

PACKAGE LEAFLET:
OXYGAN 500 mg/g POWDER FOR USE IN DRINKING WATER

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

sp veterinaria, sa
Ctra Reus Vinyols km 4.1
Riudoms (43330)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXYGAN 500 mg/g POWDER FOR USE IN DRINKING WATER

Oxytetracycline hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each g contains:

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

Excipient:

Yellow powder

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 of live weight per day.

9. ADVICE ON CORRECT ADMINISTRATION

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).

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label
The expiry date refers to the last day of that month.

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

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

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.

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.

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.

Overdose (symptoms, emergency procedures, antidotes):

See "Adverse reactions (frequency and seriousness)" section.

Incompatibilities:

In the absence of compatibility studies, this veterinary product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

Package size:
Bag of 1 kg
Bag of 100 g

Not all pack sizes may be marketed.