SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dabicycline 500 Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of product contains:

Active substance
Oxytetracycline hydrochloride 500 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for solution for use in drinking water, and in feed for fish.

4. CLINICAL PARTICULARS

4.1 Target species

Broilers, turkeys, and fish

4.2 Indications for use, specifying the target species

Treatment of infections caused by micro-organisms sensitive to oxytetracycline in chicken broilers, turkeys, and fish.

4.3 Contraindications

Not to be used in layer hens.
Do not use in cases of hypersensitivity to oxytetracycline or any other substance from tetracyclines group.
Do not use in cases of known tetracycline resistance.
Do not administer to fish together with growth promoters or other antibiotics.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i) Special precautions for use in animals

This powder should be dissolved in water before use.

Use of the product should be based on susceptibility testing of bacteria isolates from the animal. If not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Official, national and regional 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 oxytetracycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross-resistance.
Prolonged or repeated use should be avoided as these practices can enforce development and spread of the bacterial resistance. This is particularly likely in enterobacteria and *Salmonella spp.*, many of which are already resistant.
As eradication of the target pathogens may not be achieved, medication should be combined with good management practices, e.g., good hygiene, proper ventilation, no overstocking.
Extensive resistance to oxytetracycline has been recognized in poultry isolates of strains form *E. Coli*, *Salmonella spp.*, *Campylobacter spp.*, and *Enterococcus spp*.
The product should only be used where culture and sensitivity testing have demonstrated that it is likely to be effective.
Sick animals may have a reduced appetite and an altered drinking pattern and should, if necessary, be medicated parenterally.

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

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Avoid inhaling dust when handling the product until complete solubilization in water.
Use in a well-ventilated area away from draughts.
Avoid contact with skin and eyes.
Personal protective equipment consisting of latex and nitrile gloves, eye protection 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) 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.
Wash hands and contaminated skin immediately after handling the product.
Do not smoke, eat or drink while handling the product.

iii) Other precautions
None.

4.6 Adverse reactions (frequency and seriousness)

As for all other tetracyclines, side effects such as gastro-intestinal disorder and less frequently, allergic and photosensitivity reactions are very rare (less than 1 animal in 10,000 animals treated, including isolated reports) according to pharmacovigilance data.

Side effects can be reported to the Ministry of Health by clicking on the link “Report adverse effects and problems associated with medications and drugs” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

4.7 Use during pregnancy, lactation or lay

Laboratory studies in animals have not produced any evidence of embryotoxicity or teratogenic effects.
Not to be used in layer hens.
This product may be used on brood stock.

4.8 Interaction with other medicinal products and other forms of interaction

Divalent or trivalent cations (Mg, Fe, Al, Ca) may chelate with tetracyclines. The tetracyclines should not be administered with antacids, gels containing aluminum, preparations containing vitamins or minerals as insoluble complexes will be formed, which decreases the absorption of the antibiotic.

4.9 Amount(s) to be administered and administration route

Broilers and Turkeys:
The uptake of medicated drinking water depends on the clinical and physiological conditions of the animals. In order to obtain the correct dosage, the concentration of oxytetracycline must be adjusted by calculating the required mean daily water consumption.

Broilers: 40-60 grams of Dabicycline 500 Veterinary per 100 liters of drinking water for 3-5 days as the sole source of drinking water.

Turkeys: 100 grams of Dabicycline 500 Veterinary per 100 liters of drinking water for 3-5 days as the sole source of drinking waterTo ensure a correct dosage, body weight should be determined as accurately as possible to avoid under dosing.

The use of suitability calibrated weighing equipment is recommended if part packs are used. The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours.
Medicated drinking water should be freshly prepared every 12 hours.

Fish: 150 grams of Dabicycline 500 Veterinary per 1 ton live weight for 10 days.
The product is for administration only through the feed by mixing with manufactured feed prior to feeding. Feeding rates will vary according to the water temperature and it may therefore be more convenient to medicate on the basis of a fixed rate, e.g. 1% of bodyweight, with the extra daily feed requirement being met by unmedicated food.
Method of mixing:
Weigh out appropriate amounts of fish pellets and product and mix well together in a dry state.

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

None known

4.11 Withdrawal periods

Broilers and turkeys: : 7 days
Eggs: do not use in laying birds producing eggs intended for human consumption
Fish: 400 ºdays (equivalet to 20 days at 20ºC.)

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracycline
ATCvet code: QJ01AA06.

5.1 Pharmacodynamic properties

The oxytetracycline links reversibly to the ribosomal subunit 30S receptors, this leading to a blockage of the union between aminoacyl-tRNA to the site corresponding to the mRNA-ribosome complex messenger.
It results in an inhibition of the protein synthesis and inhibits bacterial growth. The mainly bacteriostatic activity of oxytetracycline involves uptake of the substance into the bacterial cell which occurs by both passive and active diffusions. The main mechanism of resistance is due 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 mainly active against Gram-positive and Gram negative bacteria, aerobic and anaerobic, as well as against mycoplasma, the Chlamydia and Rickettsiae and some protozoa.

Acquired resistance to oxytetracycline has been reported. This resistance is usually of plasmid origin. Cross-resistance to other tetracyclines is possible. The prolonged or repeated use of oxytetracycline as well as continuous treatment with low doses of oxytetracycline may also cause increased resistance to other antibiotics due to potential co-resistance with other antimicrobials.

Four resistance mechanisms acquired by microorganisms against tetracyclines in general have been reported: decreased accumulation of tetracyclines (decreased permeability of the bacterial cell wall and active efflux), protein protection of the bacterial ribosome, enzymatic inactivation of the antibiotic and rRNA mutations (preventing the tetracycline binding ribosome).

5.2 Pharmacokinetic particulars

The oral absorption of oxytetracycline is low. The mean values of oral absorption of oxytetracycline are 3-5% in pigs and 48% in turkeys.
This bioavailability can be reduced in the presence of food in the stomach as oxytetracycline leads to the formation of insoluble chelates with divalent or trivalent cations (Mg, Fe, Al, Ca).
The oxytetracycline binds variably to plasma proteins according to the species (75%). Its distribution is large. The oxytetracycline diffuses throughout the body, the highest concentrations have been found in the kidneys, liver, spleen and lungs. The oxytetracycline crosses the placental barrier.
Oxytetracycline is excreted unchanged mainly via urine. It is also excreted via bile but a high proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid.

6.2 Major incompatibilities

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

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Do not store below 25°C

6.5 Nature and composition of immediate packaging

Aluminum bags containing 250g, 500g, 1kg, 5kg
Not all pack sizes may be marketed.

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.

7. MARKETING AUTHORIZATION HOLDER

Abic Veterinary Products, P.O.B 489, Beit Shemesh, Israel

8. MARKETING AUTHORISATION NUMBER

072-62-91206-03

This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in October 2023