

PATIENT LEAFLET FOR A VETERINARY PREPARATION

The medicine is dispensed with a
veterinarian's prescription only
For animal use only

1. Name of the veterinary medicinal product, its form and strength

Dabicycline 500 Veterinary

Powder for solution

For administration in drinking water
for broiler chickens and turkeys,
in food for fish

2. Active ingredient

Each 1 gram contains:

Oxytetracycline hydrochloride 500 mg

For the list of inactive ingredients, see section
13 "Further information".

3. What is the medicine intended for

The medicine is intended for the treatment of
diseases and infections caused by bacteria
sensitive to oxytetracycline in broiler chickens,
turkeys and fish.

Therapeutic group: Broad-spectrum
antibiotics from the tetracycline group.

4. Contraindications

Do not use in layer chickens.

Do not use in case of hypersensitivity to
oxytetracycline or other substances from the
tetracycline group.

Do not use in cases of known tetracycline
resistance.

In fish, do not administer the preparation
together with growth promoters or other
antibiotics.

5. Side effects

As for all other tetracyclines, side effects
such as gastro-intestinal disturbances and
less frequently, allergic and photosensitivity
reactions are very rare (less than one in 10,000
treated animals).

If you notice any side effects, even those that
are not mentioned in this leaflet, or if there is
suspicion that the medicine is not effective,
please report to your veterinarian.

Side effects can be reported to the Ministry
of Health by clicking on the link "Report Side
Effects of Drug Treatment" 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>

6. Target animals

Broiler chickens, turkey and fish.

7. Route of administration and dosage

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

Turkeys: 100 grams Dabicycline 500 Veterinary
per 100 liters drinking water for 3-5 days, as the
sole drinking source.

Fish: 150 grams Dabicycline 500 Veterinary per
1 ton live fish weight for 10 days.

8. How to use the preparation

Poultry: Dissolve the appropriate amount of
powder in the appropriate amount of drinking
water.

Serve as the sole source of drinking water.
Prepare a fresh solution every 12 hours.

Fish: Serve mixed with the fish feed.

Feed consumption changes with water
temperature. To adjust the dosage to the feed
consumption rate, consult a veterinarian.

9. Withdrawal period

Broiler chickens: 7 days

Turkeys: 7 days

Fish: 400° days = 20 days at 20°C

10. Warnings

- Special warnings for use in target animal

Poultry:

Use of the product should be based on
susceptibility testing of bacteria isolates from
the animal. If this is not possible, the treatment
should be based on local epidemiological
information about susceptibility of the target
bacteria. Official policies regarding treatment
with antimicrobial products should also be taken
into account. Use of the product deviating from
the instructions in the leaflet may increase the
prevalence of resistance to oxytetracycline and
decrease the effectiveness of treatment with
tetracyclines, due to the possibility of cross-
resistance.

Prolonged or repeated use of oxytetracycline
should be avoided as these practices can lead
to development and spread of the bacterial
resistance.

As optimal treatment efficacy in eradication of
the target pathogen may not be achieved, the
pharmaceutical treatment should be combined
with good management practices, e.g., good
hygiene, proper ventilation, and avoidance of
overstocking.

Extensive resistance to oxytetracycline has
been recognized in poultry isolates of *E. coli*,
Salmonella spp., *Campylobacter* spp., and
Enterococcus spp. Therefore, extra caution
should be exercised when these bacteria are
involved. The medicine 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. If necessary,
parenteral treatment is needed.

Fish:

The product is intended for administration only
through the feed, by mixing it with the feed prior
to feeding.

If there is no improvement within 24-48 hours of
the start of treatment, a new evaluation should
be performed.

- Special warnings regarding the safety of use of this medicine in animals
- Special warnings regarding the safety of the person handling the product

People with known hypersensitivity to
tetracyclines should avoid contact with the
product. Avoid inhaling the powder when
handling the product until it is fully solubilized
in the water. Use the medicine in a well-
ventilated area and in a place protected from
drafts. Avoid contact with the skin and eyes.
Use latex or nitrile gloves, protective goggles
and a dust mask (European Standard EN149
or a mask with Standard EN 140 with an EN 143
filter) and suitable protective clothing. In case
of accidental eye or skin contact, rinse with a
large amount of clean water. If irritation occurs,
seek medical advice and show the product
leaflet to the attending physician. Swelling of
the face, lips or eyes, and difficulty breathing are
serious effects that require immediate medical
treatment. Hands and skin that were exposed
to the product should be washed immediately
after contact. Do not smoke, eat or drink while
handling the product.

- Additional warnings
- Pregnancy and lactation of the treated animal

Studies in laboratory animals did not find any
evidence of toxicity or teratogenic effects.

Do not use in layer chickens.

- Interactions with other medicines, and other forms of interactions

Divalent or trivalent cations (Mg, Fe, Al, Ca)
can form chelates with tetracyclines. Do
not administer tetracyclines with antacids,
aluminum-containing gels, products that contain
vitamins or minerals as insoluble complexes
that reduce absorption of the medicine may
be formed.

- Overdosage

None known.

- Incompatibility

Due to lack of compatibility studies, do not mix
this medicine with other veterinary medicinal
products.

11. Storage instructions

- Avoid poisoning! This medicine, and any other
medicine, should be kept in a safe place out of
the reach and sight of children and/or infants
in order to avoid poisoning.

- Do not use the medicine after the expiry date
(exp. Date) that appears on the package. The
expiry date refers to the last day of that month.

Storage conditions: below 25°C.

12. Instructions for the disposal of the preparation/preparation remnants after use

All remnants of a veterinary product or any
waste obtained from use of a veterinary product
should be disposed of as toxic waste, do not
discard in the wastewater.

13. Further information

In addition to the active ingredient, the medicine
also contains an inactive ingredient: Citric acid

- Package content: yellowish powder.
- Package sizes: 250 g, 500 g, 1 kg, 5 kg bag.
Not all package sizes may be marketed.

Manufacturer and license holder: Abic
Veterinary Products Ltd., P.O.B. 489, Bet
Shemesh Industrial Zone.

**This leaflet was checked and approved by
the Ministry of Health on:** 10/2023

**Registration number of the medicine in the
National Drug Registry of the Ministry of
Health:** 0726291206-03