PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

{NATURE/TYPE}

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

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L
Les Corts, 23
08028 Barcelona
SPAIN

Manufacturer responsible for batch release:
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MAXYL 500 mg/g POWDER FOR USE IN DRINKING WATER FOR CHICKENS, TURKEYS, DUCKS AND PIGS
amoxicillin trihydrate

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

Each gram contains:

Active substance:
Amoxicillin.....436 mg

Equivalent to 500 mg amoxicillin trihydrate

A white powder. Clear and colourless liquid when in solution.

4. PACKAGE SIZE

400 g bag
1kg bag
Box with 15 bags of 1kg

5. INDICATION(S)

Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.
Pigs: For the treatment of pasteurellosis.

6. CONTRAINDICATIONS

This product should not be administered to rabbits, guinea pigs, hamsters, gerbils or any other small herbivore.
Do not use in in cases of hypersensitivity to penicillins or other ß-lactam antibiotics or to any of the excipients.
Do not use in animals with renal disease including anuria or oliguria.

7. ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity reactions which may rarely be serious.
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.

8. TARGET SPECIES

Chickens, turkeys, ducks and pigs.

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

In drinking water use.

Prepare the solution with fresh potable water immediately before use. Any medicated water which is not consumed within 12 hours should be discarded and the medicated drinking water replenished.
In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.

The following formula may be used to calculate the required concentration of product (in milligrams of product per litre of drinking water):

x mg product per kg bodyweight per day	X	mean bodyweight (kg) of animals to be treated	= **x** mg product per litre drinking water
mean daily water consumption (l) per animal			

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The uptake of medicated water depends on the clinical condition of the animal. In order to obtain the correct dosage, the concentration of amoxicillin has to be adjusted taking into account water intake.

Chickens

The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight per day (corresponding to 30 mg product/kg bodyweight/day).

The total period of treatment should be for 3 days or in severe cases for 5 days.

Ducks

Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight per day (corresponding to 40 mg product/kg bodyweight/day) for 3 consecutive days.

Turkeys

Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight per day (corresponding to 30-40 mg product/kg bodyweight) for 3 days or in severe cases for 5 days.

Pigs

Administer in the drinking water to give 20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 40 mg product/kg bodyweight) daily for up to 5 days.

10. ADVICE ON CORRECT ADMINISTRATION

After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

11. WITHDRAWAL PERIOD

Meat and offal:

Chickens	1 day
Ducks	9 days
Turkeys	5 days
Pigs	2 days

Not authorised for use in laying birds producing eggs for human consumption or within 3 weeks of onset of laying.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30ºC.

Keep the bags tightly closed.

EXP {month/year}

Do not use this veterinary medicinal product after the expiry date which is stated on the bag after “EXP”. Shelf life after first opening the container: 3 months

Once opened, use by...

Shelf life after dilution or reconstitution according to directions: 12 hours

Once diluted or reconstituted use by…

13. SPECIAL WARNING(S)

Special warnings for each target species

None

Special precautions for use in animals

Not effective against beta-lactamase producing organisms.

Pigs: The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead.

Official, national, and regional antimicrobial policies should be taken into account when the product is used.

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.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the amoxicillin and may decrease the effectiveness of the treatment.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion, or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity the active substance or if you have been advised not to work with such preparations should avoid contact with the veterinary medicinal product.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to ENl43.

Wear gloves during preparation and administration of medicated water or liquid feed

Wash any exposed skin after handling the product or medicated water or feed. Wash hands after use.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.

Use only according to the benefit/risk assessment of the responsible veterinarian.

Lay:

Do not use in birds producing eggs for human consumption or within 3 weeks of onset of laying.

Interaction with other medicinal products and other forms of interaction

The product should not be administered with antibiotics that have a bacteriostatic mode of action, such as tetracyclines, macrolides, sulphonamides.

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

No problems with overdosage have been reported. Treatment should be symptomatic, and no specific antidote is available.

Incompatibilities

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

14. 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 products should be disposed of in accordance with local requirements.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

16. OTHER INFORMATION

Pack sizes:

400 g bag

1kg bag

Box with 15 bags of 1kg

Not all pack sizes may be marketed.

For animal treatment only.

To be supplied only on veterinary prescription.

Marketing Authorisation Number(s)

Vm 32509/4019

Lot {number}

Approved 24 June 2021