

Part IB-2

LABELLING

**OCTACILLIN
POWDER FOR USE IN DRINKING WATER
FOR CHICKENS**

**The full text will be printed on the sachet/bag
Format used is specially for this type of labelling**

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

IMMEDIATE PACKAGE

LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Octacillin 697 mg/g powder for use in drinking water for chickens, amoxicillin

2. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Composition per gram product

Active Substance: Amoxicillin 697 mg corresponding to 800 mg amoxicillin trihydrate

3. PHARMACEUTICAL FORM

Powder for use in drinking water

White to pale yellow-white powder

4. PACKAGE SIZE

100 g / 250 g / 500 g / 1.0 kg.

5. TARGET SPECIES

Chicken (excluding laying birds producing eggs for human consumption).

6. INDICATION(S)

Treatment of infections in chickens caused by bacteria susceptible to amoxicillin.

Not effective against beta-lactamase producing organisms.

7. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to penicillin or other substances of the beta-lactam group.

Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.

8. ADVERSE REACTIONS

Hypersensitivity reactions may occur.

If you notice any serious effects or other effects not mentioned in this product information, please inform your veterinary surgeon or pharmacist.

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

The product is indicated for oral administration in the drinking water. The use of suitably calibrated weighing equipment for the administration of the calculated amount is recommended.

The recommended dosage is 10-20 mg of the product per kg live weight (8-16 mg/kg amoxicillin trihydrate) per day. The higher dose is advised when treating severe infections. Treatment should be given for a period of 3-5 consecutive days.

The following formula may be used to calculate the amount of product required per day:

$$\text{gram product per day} = \frac{\text{number of birds} \times \text{average live weight (kg)}}{50 \text{ (for 20 mg/kg) or } 100 \text{ (for 10 mg/kg)}}$$

If the required amount of product is calculated by the total daily water intake, the following is a guide:

- Birds 0-4 weeks of age: 6-12 g product / 100 litres water uptake/day
- Birds older than 4 weeks: 10-20 g product / 100 litres water uptake/day

Total daily dose of product should be administered once daily in drinking water, in an amount of drinking water, that will be consumed within approximately 2 hours. Maximum solubility of the product in water is approximately 6 g/litre.

If continuous medication is preferred, then the drinking water should be refreshed with medicated water twice daily. Any medicated water, which is not consumed within 12 hours, should be discarded. To ensure a correct dosage body weight should be determined as accurately as possible to avoid under-dosing. The uptake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted accordingly.

10. WITHDRAWAL PERIODS

Meat and offal: 1 day

Eggs: Not authorised for use in laying birds producing eggs for human consumption.

11. SPECIAL WARNINGS

Special precautions for use in animals

Use of the product should be based on susceptibility testing and it should take into account official and local antimicrobial policies.

Inappropriate use of the product may increase the prevalence of bacteria resistance to amoxicilline and may decrease its effectiveness

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 cause cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

- People with known hypersensitivity to penicillin or cephalosporin should avoid contact with the product.
- Handle this product with great care to avoid exposure, taking all recommended precautions. Wear protective clothing, impervious gloves and either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with a filter to EN 143 when mixing and handling the product. Wash hands after use.
- 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.

Use during lay

Do not use in birds in lay producing eggs for human consumption. Use in breeders only according to the benefit / risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction

Amoxicillin exerts its bactericidal action by inhibition of bacterial cell wall synthesis during

multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (e.g. tetracyclines) which inhibit multiplication. In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

No effects known.

12. EXPIRY DATE

EXP {month/year}; Do not use after the expiry date stated on the label after EXP.

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions prior to opening. After opening, any remaining content can be stored for 3 months if stored dry and re-closed with clip (after folding the edge of the opened sachet).

Once opened/broached, use by:

As metal tanks may negatively influence stability of the product, metal tanks should not be used for storage of solutions.

- Shelf-life after first opening the immediate packaging: 3 months

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

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

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

15. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

Prescription only medicine

16. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

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

Eurovet Animal Health BV, Handelsweg 25, 5531-AE Bladel, The Netherlands

18. MARKETING AUTHORISATION NUMBER(S)

19. MANUFACTURER’S BATCH NUMBER

Lot {number}

20. DATE ON WHICH THE TEXT WAS LAST APPROVED

XX / XX / XXXXX

21. OTHER INFORMATION

Authorised pack sizes: 100 g, 250 g, 500g, 1.0 kg

Not all pack sizes may be marketed.