PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Sachet/bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each gram contains:
Amoxicillin (as Amoxicillin trihydrate) 697 mg

White to pale yellow-white powder.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Chicken.

5. INDICATIONS FOR USE

Indications for use

Treatment of infections in chickens caused by bacteria susceptible to amoxicillin.
Not effective against beta-lactamase producing organisms.

6. CONTRAINDICATIONS

Contraindications

Do not use in known cases of hypersensitivity to penicillin or other substances of the beta-lactam group or to any of the excipients.
Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies. Inappropriate use of the product may increase the prevalence of bacteria resistance to amoxicillin 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.
1. People with known hypersensitivity to penicillin or cephalosporin should avoid contact with the veterinary medicinal product.
2. Handle this veterinary medicinal 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.
3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice immediately and show the package leaflet or 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.

Laying birds:
Do not use in birds in lay. Use in breeding birds only according to the benefit-risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:
The bactericidal effect of amoxicillin is counteracted by pharmaceuticals with a bacteriostatic effect. Synergism occurs with ß-lactam antibiotics and aminoglycosides.

Overdose:
None known.

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

8. ADVERSE EVENTS

Adverse events

Chickens:

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reactions

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the

marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use.
The recommended dosage is 7-14 mg amoxicillin per kg bodyweight (corresponding to 8-16 mg amoxicillin trihydrate per kg body weight, i.e. 10-20 mg of the veterinary medicinal product per kg body weight) per day administered in the drinking water. The higher dose is advised when treating severe infections. Treatment should be given for a period of 3-5 consecutive days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{10-20 mg veterinary medicinal product / kg body weight / day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{mg veterinary medicinal product per litre of drinking water}$$

It is recommended that the veterinary medicinal product be administered once daily in the drinking water.
It is advisable to restrict drinking water for approximately 2 hours (less in hot weather) prior to medication.

To ensure a correct dosage body weight should be determined as accurately as possible.
The intake 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.
The use of suitably calibrated weighing equipment for the administration of the calculated amount of product is recommended.

The calculated total daily amount of powder is dissolved in 5-10 litres of drinking water and stirred until evenly dispersed. This solution is then added, whilst stirring, into 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, however, continuous medication is preferred then the drinking water should be refreshed with medicated water at least twice daily. In all cases ensure that there is no access to unmedicated water whilst medicated water is being offered. When all medicated water has been consumed, turn on the normal water supply again. Any unused medicated water should be discarded after 12 hours.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 1 day
Not for use in birds producing eggs for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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). As metal tanks may negatively influence stability of the product, metal tanks should not be used for storage of medicated drinking water.

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation numbers
MA numbers to be completed nationally.

Pack sizes

Authorised pack sizes: 100 g, 250 g, 500g, 1.0 kg
Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

To be completed nationally.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

To be completed nationally.

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

Manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25
5531-AE Bladel
The Netherlands

<Local representatives <and contact details to report suspected adverse reactions>:>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. OTHER INFORMATION

<Other information>

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after dissolution or reconstitution according to directions: 12 hours.
Once opened/broached, use by:

21. BATCH NUMBER

Lot {number}