SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Amoxicillin (as Amoxicillin trihydrate Ph. Eur.) 697 mg/g
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for use in drinking water
White to pale yellow-white powder

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

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.

4.4 Special warning for each target species.

None.

4.5 Special precautions for use

i. 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.

ii. 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 product.
2. 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.
3. 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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur.

4.7 Use during pregnancy, lactation or 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

4.8 Interaction 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. Synergism occurs with ß-lactam antibiotics and aminoglycosides.

4.9 Amounts to be administered and administration route

The recommended dosage is 10-20 mg of the product per kg live weight (8-16 mg/kg amoxicillin trihydrate) 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. The following formula may be used to calculate the amount of product required per day:

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

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

It is recommended that the 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. 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 scattered onto the surface of 5-10 litres of clean 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.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. 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.

4.10 Overdose (symptoms, emergency procedures, antidotes)

None known.

4.11 Withdrawal periods

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterial, Penicillin

ATC vet code: QJ01CA04

5.1 Pharmacodynamic properties

The active ingredient, amoxicillin, is a bactericidal antibiotic of the beta-lactam class. It acts by inhibition of bacterial cell wall synthesis. Amoxicillin is not resistant to the action of beta-lactamases, which can hydrolyse the molecules causing the beta-lactam ring structure to open, rendering it antibiotically inactive.
The information for staphylococcal beta-lactamase is encoded in a plasmid and may be transferred by bacteriophage to other bacteria. In G- bacteria beta-lactamases are encoded in either chromosomes or in plasmids and they may be constitutive or inducible. Plasmids may be transferred between bacteria through conjugation.
Some bacteria are intrinsically resistant to amoxicillin, because they have decreased affinity for the antibiotic. Decreased affinity may also be acquired by homologous recombination between genes of different species. Other instances of bacterial resistance are caused by the inability of the agent to penetrate to its site of action (some G- bacteria) or by energy dependent efflux systems for pumping the antibiotic out of the bacteria.
In general, practical development of resistance in vitro against amoxicillin like all penicillins occurs slowly and stepwise, with an existing cross-resistance with other penicillins which is of practical significance by staphylococci.
Both long term treatment and sub-therapeutic dosages can select for antimicrobial resistance. Amoxicillin is generally active against some Gram-negative and most

Gram-positive bacteria e.g. penicillin sensitive Staphylococci, Streptococci, Pasteurella spp., Clostridium spp., Salmonella spp., *Haemophilus paragallinarum,* and *E. coli.* Resistance amongst *E. coli* strains is not uncommon.

5.2 Pharmacokinetic properties

Following oral medication amoxicillin is rapidly absorbed. Maximum amoxicillin concentrations (between 1-2 µg/ml) are reached within 1-2 hours. Serum protein binding is low. Amoxicillin is widely distributed throughout the body. Amoxicillin is mainly eliminated via the kidneys in the active form. A smaller part of the administered dose of amoxicillin is excreted in the bile. Plasma half-life time of amoxicillin in chickens is approximately 1 hour.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium carbonate monohydrate
Sodium citrate
Silica colloidal anhydrous

6.2 Incompatibilities

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

6.3 Shelf life

- Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
- Shelf-life after first opening the immediate packaging: 3 months
- Shelf-life after dilution or reconstitution according to directions: 12hours

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

6.5 Nature and composition of immediate packaging

Aluminium sachets consisting of the following materials: on the outside a white layer, inside different transparent layers, a sub-layer of aluminium and an inner layer of polyethylene. Pack sizes are 100, 250, 500 and 1000 g.

Aluminium sachets consisting of the following materials: on the outside a plastic layer, inside layers of aluminium and polyamide and an inner layer of polyethylene. Pack sizes are 100, 250, 500 and 1000 g.

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

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

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.,
Handelsweg 25, 5531 AE Bladel, The Netherlands.
PO Box 179, 5530 AD Bladel, The Netherlands.

8. MARKETING AUTHORISATION NUMBER

Vm 16849/4004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date: 06 September 2004

10. DATE OF REVISION OF THE TEXT

Date: September 2012