

## **ANNEX I**

### **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**

Each gram contains:

**Active substance:**

Amoxicillin (as Amoxicillin trihydrate) 697 mg

**Excipients:**

Qualitative composition of excipients and other constituents
Sodium carbonate monohydrate
Sodium citrate
Silica colloidal anhydrous

White to pale yellow-white powder.

**3. CLINICAL INFORMATION****3.1 Target species**

Chickens.

**3.2 Indications for use for each target species**

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

**3.3 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.

**3.4 Special warnings**

None.

**3.5 Special precautions for use**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.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Chickens:

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reactions
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Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Laying birds:

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

### 3.8 Interaction 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  $\beta$ -lactam antibiotics and aminoglycosides.

### 3.9 Administration routes and dosage

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.

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:

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

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.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

None known.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

To be completed nationally.

### **3.12 Withdrawal periods**

Meat and offal: 1 day

Not for use in birds producing eggs for human consumption.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QJ01CA04.

### **4.2 Pharmacodynamics**

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 Gram- 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 Gram- 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 *Escherichia. coli*. Resistance amongst *Escherichia. coli* strains is not uncommon.

### **4.3 Pharmacokinetics**

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.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 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 dissolution or reconstitution according to directions: 12 hours.

### **5.3 Special precautions for storage**

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.

### **5.4 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.

#### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

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.

### **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

To be completed nationally.

### **7. MARKETING AUTHORISATION NUMBER(S)**

To be completed nationally.

### **8. DATE OF FIRST AUTHORISATION**

To be completed nationally.

### **9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

To be completed nationally.

### **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).