# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bioamoxi 500 mg/g powder for oral solution for chicken

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active Substance
Amoxicillin (as amoxicillin trihydrate) 500 mg

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Powder for oral solution.
A fine, almost white, homogenous powder.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Broiler chickens.

### 4.2 Indications for use, specifying the target species

In broiler chickens:
- At the group level where disease is present: prevention of clinical colibacillosis due to *Escherichia coli* susceptible to amoxicillin.

### 4.3 Contraindications

Do not use in animals known for their susceptibility to penicillin or other substances of the beta-lactam group.
Do not use in lagomorphs such as rabbits, guinea-pigs, hamsters and gerbils.
Do not use in ruminants and horses ß-Lactam-resistance in *Escherichia coli*.

### 4.4 Special warnings for each target species

See section 4.11.

### 4.5 Special precautions for use

**Special precautions for use in animals**
Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious.

The use of BIOAMOXI should be based on susceptibility testing because of reported resistance (up to 50 %) in *Escherichia coli* isolated from chickens. Inappropriate use of the product may increase the prevalence of bacteria resistance to amoxicillin and may decrease its effectiveness.
Official, national and regional antimicrobial policies should be taken into account when the product is used.

**Special precautions to be taken by the person administering the product to animals**
Penicillins and cephalosporins may induce hypersensitivity reactions (allergy) after injection, inhalation, ingestion or contact with the skin. Cross-hypersensitivity to cephalosporins and penicillins may be observed. Allergic reactions to these substances may be particularly hazardous.

Hypersensitive persons should avoid all contact with the product.

When handling the product, avoid inhaling the dust and avoid contact with the skin and eyes. Wear a mask, safety glasses and protective gloves when reconstituting the solution. Wash exposed skin after preparation.
Wear protective gloves when administering the solution. Wash exposed skin after administering the solution.
In case of accidental projection into the eyes, rinse abundantly with water. Contact a physician if a skin rash is observed.
Contact a physician immediately in the event of oedema of the face, lips or eyes, or if breathing difficulties are encountered.

**4.6 Adverse reactions (frequency and seriousness)**

Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious.

**4.7 Use during pregnancy, lactation or lay**

See section 4.11.

**4.8 Interaction with other medicinal products and other forms of interactions**

Not to be used simultaneously with neomycin since it blocks the absorption of oral penicilins. The bactericidal effect of amoxicillin is neutralised by the simultaneous use of bacteriostatic antibiotics.

**4.9 Amounts to be administered and administration route**

20 mg of amoxicillin per kg bodyweight per day for 5 consecutive days by the oral route, i.e. 40 mg of powder per kg bodyweight per day for 5 consecutive days.

The uptake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of BIOAMOXI should be adjusted accordingly.
The following calculation should be made to determine the quantity in gram Bioamoxi to be added in 1000 litres of water:

mg Bioamoxi/ kg body weight/day x mean body weight of individual animals (kg) x number of animals
_____
Total water consumption of the house (litres) at the previous day

= mg Bioamoxi/l = g Bioamoxi/1000 l water

Stirring should be performed for 10 minutes to solve the product completely.
The solution should be prepared freshly every 12 hours
No other source of drinking water should be available during the medication period.

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

No adverse effects were observed at a dose corresponding to 5 fold the therapeutic dose.

**4.11 Withdrawal period(s)**

Meat and offal: 6 days.

Do not use within 4 weeks of onset of the laying.
Not authorised for use in laying birds producing eggs for human consumption.

It should be recalled that no foodstuffs of animal origin may be delivered for human consumption during the treatment period, whatever the withdrawal time.

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: antibacterial for systemic use

ATCvet code: QJ01CA04

**5.1 Pharmacodynamic properties**

Amoxicillin is a semi-synthetic penicillin derived from the 6 APA nucleus (6-aminopenicillinic acid). It is a weak acid, poorly fat soluble and stable in acid media.

Amoxicillin causes alterations in the bacterial cell wall that result secondarily in osmotic lysis of the bacterium. Amoxicillin exerts bactericidal effect against susceptible bacteria, such as *Escherichia coli*.

β-lactamase-producing strains are not sensible to amoxicillin.

Resistance manifests primarily through the production of bacterial β-lactamases.

**5.2 Pharmacokinetic particulars**

Following a single dose of Bioamoxi at a dose of 10 mg amoxicillin per kg by oral gavage, amoxicillin is extensively absorbed with bioavailability of about 100%. Amoxicillin is rapidly absorbed with peak plasma levels of about 1 mcg/ml being observed at the first sampling time point (30 minutes). The apparent elimination half-life is 2.3 hours. The limit of quantitation (20 ng/ml) is reached 6 hours after administration by the intravenous route and 8 hours after administration by the oral route. The active substance is very widely distributed (volume of distribution about 12 l/kg). After the dosage regimen recommended by the marketing authorisation holder (20 mg/kg/day by continuous administration) no accumulation was noted. When the treatment was discontinued, the concentrations decreased very rapidly, falling below the limit of quantitation four hours after the end of treatment.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Sodium carbonate monohydrate (E500)
Borax (E285)
Glycine (E640)
Colloidal anhydrous silica
Sodium lauryl sulphate
Disodium edetate
Lactose monohydrate

**6.2 Major incompatibilities**

None known.

**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 dissolution in drinking water: 12 hours.

**6.4 Special precautions for storage**

Do not store above a temperature of 30°C.Keep the primary container tightly closed.

**6.5 Nature and composition of immediate packaging**

**100g sachets** made up of 3 layers. The secondary packaging is a cardboard box containing 10 sachets with 3 layers of LDPE, aluminium, and white craft paper.

**250g jars** made of HDPE, closed with HDPE lids and fitted with HDPE caps

**500g jars** made of HDPE, closed with HDPE lids

**1kg jars** made of HDPE, closed with HDPE lids

**2kg and 4kg bags** made up of 3 layers (LDPE, aluminium, and polyester).

**2kg and 4kg tubs** made of polypropylene, closed with polypropylene lids and containing a LDPE inner bag.

Not all pack sizes may be marketed.

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

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

**7 MARKETING AUTHORISATION HOLDER**

V.M.D. n.v/s.a.
Hoge Mauw 900
Arendonk
2370
Belgium

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA10817/001/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 10 July 2003
Date of last renewal: 10 July 2008

**10 DATE OF REVISION OF THE TEXT**