Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AMOXY ACTIVE, 697 mg/g, oral powder for pigs and chickens

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Amoxicillin	697 mg
as amoxicilline trihydrate	800 mg

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral powder.
White to off-white powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Pig and chicken (broiler, pullet, breeder).

4.2 Indications for use, specifying the target species

Pigs: Treatment of respiratory tract infections, gastro-intestinal tract infections, urogenital infections, ear necrosis, secondary infections following viral infections and septicemia caused by micro-organisms susceptible to amoxicillin
Chickens: Treatment of respiratory tract infections and gastro-intestinal tract infections caused by micro-organisms susceptible to amoxicillin.

4.3 Contraindications

Do not use in cases of hypersensitivity to penicillin or other substances of the beta-lactam group or to any of the excipients.
Do not use in the presence of ß-lactamase-producing bacteria.
Do not use in lagomorphs and rodents such as guinea pigs, hamsters or gerbils.
Do not use in animals with serious kidney malfunction including anuria and oliguria.
Do not use in ruminants or horses.

4.4 Special warnings for each target species

Sick animals have an altered drinking behaviour and should be medicated parenterally where applicable.

4.5 Special precautions for use

Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the amoxicillin and may decrease the effectiveness of the treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillins 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 beta-lactam antibiotics should avoid contact with the veterinary medicinal product.
Handle this product with great care to avoid exposure, taking all recommended precautions.
Wear 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.
In case of contact with eyes or skin, wash immediately with water.
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)

In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports) the following adverse reactions may appear:
- hypersensitivity reactions, the severity varying from skin rash to anaphylactic shock;
- gastrointestinal symptoms (vomiting, diarrhoea).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

Do not combine with bacteriostatic antibiotics.
Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.
Synergism occurs with ß-lactam antibiotics and aminoglycosides.

4.9 Amounts to be administered and administration route

For oral administration
In drinking water use and in-feed use in pigs.
In drinking water use in chicken.

Pig:
The recommended dose is 11.2 mg amoxicillin per kg of body weight daily (corresponding to 16.1 mg of the veterinary medicinal product per 1 kg of body weight per day) given for 3 - 5 consecutive days.

Chicken:
The recommended dose is 20 mg amoxicillin per kg of body weight daily (corresponding to 28.7 mg of the veterinary medicinal product per 1 kg of body weight per day) given for 3 - 5 consecutive days.

In drinking water use
For the preparation of medicated water the body weight of the animals to be treated and their actual daily water consumption should be taken into account. Consumption may vary depending on factors like species, age, state of health, breed and husbandry system (e.g. different temperature, different light regimes). In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted accordingly.
Preparation of medicated water should provide an amount to be consumed within the next 12 hours. Any unused medicated water should be discarded after 12 hours, and freshly medicated water for the next 12 hours should be prepared.
The following formula may be used to calculate the required amount of veterinary medicinal product in mg per litre drinking water:

$$\frac{\text{… mg product/ kg body weight/day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (litre) per animal}} = \text{… mg product per litre of drinking water}$$

The veterinary medicinal product should be added to the drinking water by thorough stirring until the product is completely dissolved. Maximum solubility of the product in water is approximately 6 g/litre. Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. In free range husbandry systems animals should be kept in the stable during treatment.
Where applicable the water supply system should be cleaned appropriately after the end of the medication period to avoid intake of sub-therapeutic amounts of the active substance.

In-feed use:
The product may also be offered via the feed at the recommended daily dose. This way of administration is only intended for the treatment of individual pigs on farms where only a small number of pigs are to receive the treatment. Only the pack size of 100 g is suitable for the in-feed use.
Larger groups should be treated with medicated drinking water.
Before each administration the powder should be thoroughly mixed into a small amount of food and should be given directly to the animal before the main ration. Care should be taken that the intended dose will be completely ingested.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

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

In case of overdosing no other effects are known than mentioned in section 4.6 adverse reactions.

4.11 Withdrawal period(s)

Pigs: meat and offal: 2 days
Chickens: meat and offal: 1 day

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterials, Penicillins
ATCvet-code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin, is a broad-spectrum penicillin with bactericidal action against many Gram-positive and Gram negative bacteria. It owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

Amoxicillin is acid resistant, but is not resistant to the action of beta-lactamases.

5.2 Pharmacokinetic particulars

Amoxicillin is rapidly and almost completely absorbed from the gastrointestinal tract and is stable in the presence of gastric acids. Maximum amoxicillin concentrations 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 to give high concentrations in renal tissue and urine. A smaller part of the administered dose of amoxicillin is excreted in the bile.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium carbonate
Sodium citrate

6.2 Major 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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.
Shelf life after reconstitution in drinking water: 12 hours.
Shelf-life after addition to the feed: use immediately.

6.4 Special precautions for storage

Store below 25 ºC.
Store in the original container.

6.5 Nature and composition of immediate packaging

- Securitainer: white polypropylene container, covered with a low-density polyethylene lid.
  The securitainer contains 100g, 250g, 500g or 1 kg of product.
- Bucket: white polypropylene bucket provided with a polypropylene lid.
  The bucket contains 1, 2.5 or 5 kg of product.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10791/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd August 2014
Date of last renewal: 24th May 2019

10 DATE OF REVISION OF THE TEXT

May 2019