1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Octacillin 800 mg/g powder for use in drinking water for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Amoxicillin	697 mg
equivalent to amoxicillin trihydrate	800 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium carbonate monohydrate
Sodium citrate
Colloidal anhydrous silica

White to pale yellow-white powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

Treatment of infections caused by bacteria sensitive to amoxicillin:
Pigs**:** Pleuropneumonia caused by *Actinobacillus pleuropneumoniae,*
Meningitis caused by *Streptococcus suis*

3.3 Contraindications

Do not use in cases of hypersensitivity to penicillin and other substances of the ß-lactam group or to any of the excipients.
Do not use in rabbits and rodents such as guinea pig, hamster or gerbil.
Do not use in animals with serious kidney malfunction including anuria and oliguria.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. Use of the veterinary medicinal 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 veterinary medicinal product deviating from the instructions given in

the SPC may increase the prevalence of bacterial resistance to amoxicillin and may decrease its effectiveness of treatment with amoxicillin, due to the potential for cross-resistance.

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 lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this veterinary medicinal product if you know you are sensitised or if you have been advised not to work with such preparations.
Handle this veterinary medicinal product with care to avoid exposure, taking all recommended precautions. Do not smoke, eat or drink while handling the veterinary medicinal product. During preparation and administration of the medicated drinking water, skin contact with the veterinary medicinal product and inhalation of dust particles should be avoided. Wear gloves and an appropriate dust mask when applying the veterinary medicinal product. Wash hands and contaminated skin immediately after handling the veterinary medicinal product.
In the event of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning 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

Pigs:

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction* (e.g. skin rash, anaphylactic shock)

*Varying in severity. If suspected adverse reactions occur, treatment should be discontinued.

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, embryotoxic or maternotoxic effect of amoxicillin.

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.

3.9 Administration routes and dosage

In drinking water use.

Pigs:
The recommended daily dose is 16 mg amoxicillin trihydrate - corresponding to 14 mg amoxicillin per kg of body weight, i.e. 20 mg of the veterinary medicinal product per kg of body weight equivalent to 1 gram veterinary medicinal product per 50 kg body weight per day, given for 3-5 consecutive days. In case of severe infections the medication period must be prolonged to 5 days as determined by the attending veterinary surgeon.

Bolus dosage: It is recommended to administer the veterinary medicinal product once a day for a limited period of time. Shut off the drinking water system for approx. two hours (shorter time in warm weather) until the time of medication. Sprinkle the calculated daily quantity of powder on the surface of 5-10 litres water. Mix thoroughly until the powder has dissolved. Mix this solution by stirring into the volume of drinking water that will be drunk within about 2-3 hours.

Continuous treatment: The table below shows the guidelines for administering the veterinary medicinal product, assuming consumption of 100 litres drinking water a day based on a estimated water consumption of 1 litre per 10 kg of body weight in pigs under 4 months and 0.66 litre per 10 kg of body weight in pigs over 4 months.

Pigs under 4 months:	20 g powder/100 litres/day
Pigs over 4 months:	30 g powder/100 litres/day

In the case of continuous treatment, the medicated water must be changed twice daily. 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:

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

** Prepare an amount of medicated water to be consumed within the next 12 hours. Any unused medicated water should be discarded after 12 hours, and fresh medicated water - for the next 12 hours - should be prepared*

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 case of insufficient uptake of water, pigs should be treated parenterally. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted accordingly. The maximum concentration of the pre-diluted medicated water is approximately 8 grams of veterinary medicinal product per liters. The setting of the dosing device should be changed accordingly.
Make sure the animals do not have access to non-medicated water during the period when the medicated water is given. Once all the medicated water has been drunk, turn the drinking water system back on. Discard any excess medicated water after 12 hours. The use of suitably calibrated measuring equipment is recommended.

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

Not applicable

3.12 Withdrawal periods

Meat and offal: 2 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA04.

4.2 Pharmacodynamics

The active ingredient, amoxicillin, is a bactericidal, mainly time-dependant antibiotic of the betalactam class. It acts by inhibition of bacterial cell wall synthesis. Amoxicillin has a bactericidal effect on a wide range of Gram-positive and Gram-negative bacteria. The MIC_{50}/MIC_{90} of *Actinobacillus pleuropneumoniae* is 0.25µ g/ml. The MIC_{50}/MIC_{90} of *Streptococcus suis* is $\leq$ 0.03 µ g/ml.
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 in staphylococcus infections. Both long term treatment and sub-therapeutic dosages can select for antimicrobial resistance. Resistance to ß-lactam antibiotics is essentially linked to ß-lactamases which hydrolyse them.

4.3 Pharmacokinetics

With this veterinary medicinal product high amoxicillin concentrations are quickly reached in the blood. After oral administration, amoxicillin is largely absorbed (74 - 92 %).
This antibiotic is well distributed to all organs and tissues, where also high concentrations are reached. Amoxicillin is largely excreted by the kidneys in the unchanged form. A smaller part of the administered dose of amoxicillin is excreted in the bile and also in the milk.

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: 3 years.
Shelf life after first opening the immediate packaging: 1 month.
Shelf life after dilution or reconstitution according to directions: 12 hours.

5.3 Special precautions for storage

This veterinary medicinal product as packaged for sale does not require any special storage conditions.
After opening/reconstitution:
Do not store above 25ºC.

Keep the bag tightly closed in order to protect from moisture.

5.4 Nature and composition of immediate packaging

Multilayer sachets with pack sizes of 100 g, 250 g, 500 g or 1 kg. The sachets consist 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.
Multilayer sachets with pack sizes of 100 g, 250 g, 500 g or 1 kg. The sachets consist of the following materials: on the outside a polyester layer, inside layers of aluminium and polyamide and an inner layer of polyethylene.

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

Eurovet Animal Health B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10989/073/001

8. DATE OF FIRST AUTHORISATION

12 June 2020

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

03 January 2025

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).