SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Octacillin 800 mg/g powder for use in drinking water for pigs
UK, FR: Octacillin 697 mg/g powder for use in drinking water for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of powder contains:
Active substance:
Amoxicillin trihydrate 800 mg corresponding to 697 mg amoxicillin
UK, FR: Amoxicillin 697 mg equivalent to amoxicillin trihydrate 800 mg
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

Pigs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in animals with known hypersensitivity to penicillin and other substances of the ß-lactam group.
Do not use in rabbits and rodents such as guinea pig, hamster or gerbil.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to amoxicillin. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

The uptake of medication by pigs can be altered as a consequence of illness. In case of insufficient uptake of water, pigs should be treated parenterally. Do not use in animals with serious kidney malfunction including anuria and oliguria.

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 lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
Handle this product with care to avoid exposure, taking all recommended precautions. Do not smoke, eat or drink while handling the product. During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. Wear gloves and an appropriate dust mask when applying the product. Wash hands and contaminated skin immediately after handling the 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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur, the severity varying from skin rash to anaphylactic shock. If suspected adverse reactions occur, treatment should be discontinued.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals (rats, rabbits) did not show a teratogenic, embryotoxic or maternotoxic effect of amoxicillin. The safety of the product in pregnant and lactating sows was not demonstrated. Use during pregnancy and lactation should only be according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

The bactericidal effect of amoxicillin is counteracted by pharmaceuticals with a bacteriostatic effect.

4.9 Amounts to be administered and administration route

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 product per kg of body weight equivalent to 1 gram product per 50 kg body weight per day. The product is to be administered in the drinking water 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 product once a day via the drinking water 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 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 dose to be used, and the number and weight of the animals to be treated, the exact daily amount of product can be calculated. The following formula can be used to calculate the concentration of the product in drinking water:

$$\frac{\text{20 mg product / kg body weight / day} \times \text{Mean body weight (kg) of animals to be treated}}{\text{Mean water consumption (l) per animal on previous day*}} = \text{.... mg product per l drinking water}$$

** 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 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. The maximum concentration of the pre-diluted medicated water is approximately 8 grams of product per liters. The proportioner setting 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 scales is recommended for administering the calculated amount of the product.

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

No effects known.

4.11 Withdrawal period(s)

Meat and offal: 2 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ß-lactam-antibiotic, Penicillins with extended spectrum »
ATC vet code QJ 01 CA 04.

5.1 Pharmacodynamic properties

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 ≤ 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 by staphylococci. 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1. Excipients

Sodium carbonate monohydrate,
Sodium citrate,
Colloidal anhydrous silica

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

6.4. Special precautions for storage

The veterinary medicinal product as packaged for sale requires no special storage conditions.
After opening/reconstitution: Do not store above 25ºC. Any remaining content can be stored for 1 month if stored dry and re-closed with clip (after folding the edge of the opened sachet).

6.5. 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.

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 material derived from such veterinary medicinal products 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

8. MARKETING AUTHORISATION NUMBER

Vm 16849/4030

9. DATE OF FIRST AUTHORISATION

Date: 20 December 2010

10. DATE OF REVISION OF THE TEXT

Date: October 2012