PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {Sachet/100 g, 250 g, 500 g and 1.0 kg}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Octacillin 697 mg/g Powder for Use in Drinking Water for Pigs

2. COMPOSITION

Each gram contains:

Amoxicillin	697 mg
equivalent to amoxicillin trihydrate	800 mg

White to pale yellow-white powder.

3. PACKAGE SIZE

100 g
250 g
500 g
1.0 kg

4. TARGET SPECIES

Pigs.

5. INDICATIONS FOR USE

Indications for use

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

6. CONTRAINDICATIONS

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.

7. SPECIAL WARNINGS

Special warnings

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.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, embryotoxic or maternotoxic effect of amoxicillin. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:
The bactericidal effect of amoxicillin is counteracted by pharmaceuticals with a bacteriostatic effect.

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

8. ADVERSE EVENTS

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 product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system at: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Refer to section ‘Dosage for each species, route(s) and method of administration’.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 2 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation numbers and pack sizes

Vm 16849/4030

100 g / 250 g / 500 g / 1.0 kg.
Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health B.V.,
Handelsweg 25,
5531-AE Bladel,
The Netherlands

Local representatives and contact details to report suspected adverse reactions:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

Other information

POM-V

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use by…
Shelf life after first opening the immediate packaging: 1 month.
Shelf life after dilution or reconstitution according to directions: 12 hours.

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 24 April 2025