A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Sachet/100 g, 250 g, 500 g and 1.0 kg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE , IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

1 gram powder contains:
Active Substance:
Amoxicillin 697 mg
equivalent to amoxicillin trihydrate 800 mg
White to pale yellow-white powder

4. PHARMACEUTICAL FORM

Powder for use in drinking water.

5. PACKAGE SIZE

100 g / 250 g / 500 g / 1.0 kg.

6. INDICATION(S)

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

7. 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.

8. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this product information, please inform your veterinary surgeon.

9. TARGET SPECIES

Pigs.

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Pigs: The recommended daily dose is 16 mg amoxicillin trihydrate - corresponding to 14 mg of 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 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 scales is recommended for administering the calculated amount of the product.

11. ADVICE ON CORRECT ADMINISTRATION

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

12. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 2 days

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product as packaged for sale does not require any special storage conditions.
After first opening: do not store above 25˚C, keep the bag tightly closed after first opening in order to protect from moisture.

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

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.

14. SPECIAL WARNING(S)

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

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.

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.

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.

Interaction with other medicinal products and other forms of interaction:
The bactericidal effect of amoxicillin is counteracted by pharmaceuticals with a bacteriostatic effect.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes):
No effects known.

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

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

March 2021

17. OTHER INFORMATION>

Authorised pack sizes: 100 g, 250 g, 500 g, 1.0 kg.
Not all pack sizes may be marketed.

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

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

20. EXPIRY DATE

EXP {month/year}
Once opened/broached, use by _____/_____/_____

21. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4030

22. MANUFACTURER'S BATCH NUMBER

Lot {number}

Approved 06 May 2021