B. PACKAGE LEAFLET

PACKAGE LEAFLET

STRENZEN 500/125 mg/g powder for use in drinking water for pigs

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

Marketing authorisation holder:
Elanco Europe Ltd.
Lilly House
Priestley Road
Basingstoke RG24 9NL
United Kingdom

Manufacturers responsible for batch release:
Lek Pharmaceuticals d.d., Penicillin Production Plant
Perzonali 47, SI-2391 Prevalje
Slovenia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

STRENZEN 500/125 mg/g powder for use in drinking water for pigs
Amoxicillin/Clavulanic acid

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

Each gram contains:

Active substance

Amoxicillin equivalent to 573.88 mg of Amoxicillin trihydrate)	500 mg
Clavulanic acid (equivalent to 148.88 mg of Potassium clavulanate)	125 mg

Excipients
Sodium citrate, Citric acid, Mannitol

Powder for use in drinking water.
Yellowish to yellow fine powder.

4. INDICATIONS

Treatment of clinical

- respiratory tract infections caused by *Actinobacillus pleuropneumoniae, Pasteurella multocida, Streptococcus suis.*
- gastrointestinal infections caused by *Clostridium perfringens, Escherichia coli* and *Salmonella* Typhimurium

where the causative pathogens are beta-lactamase-producing strains of bacteria susceptible to amoxicillin in combination with clavulanic acid and where clinical experience and/or susceptibility testing indicates the

combination as the drug of choice.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group or to any of the excipients.
Do not use in rabbits, guinea pigs, hamsters, chinchillas, gerbils or small herbivores.
Do not use in known cases of resistance to the combination of amoxicillin and clavulanic acid.

6. ADVERSE REACTIONS

It is known that adverse reactions including mild gastrointestinal signs (diarrhoea and vomiting) and allergic reactions (skin reactions, anaphylaxis) may occur after administration of penicillins.

Anal and perineal erythema, anal irritation and diarrhoea occur rarely.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs

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

Administration in drinking water.

Give 10 mg of amoxicillin (in the form of trihydrate) and 2.5 mg of clavulanic acid (in the form of potassium salt) per kg of body weight twice daily, i.e. 2 g of product per 100 kg body weight twice daily. Treatment lasts for 5 days.

For the calculation of the amount to be administered every 12 hours the following formula can be used:
Number of pigs x average body weight (kg) x dose rate (0.02 g of product / kg body weight) twice daily.
During the twice daily treatment periods, medicated drinking water should be the only water supply available. After all the medicated drinking water has been consumed, resume the supply of unmedicated water.

To ensure a correct dosage body weight of animals should be determined as accurately as possible to avoid underdosing.

The intake of medicated drinking water depends on the clinical conditions of the animals as well as on the weather/temperature. In order to obtain the correct dosage, the concentration of the product should be adjusted accordingly.

Prepare a fresh solution prior to use.
After reconstitution the medicated drinking water has to be consumed within 24 hours.

9. ADVICE ON CORRECT ADMINISTRATION

For bulk medication twice daily: Half the calculated total daily dosage of the product is scattered onto the surface of tepid water (approximately 20 °C) and stirred until evenly dispersed. Add the required amount of water to achieve a concentration of 0.6 g – 3.0 g of product per liter of drinking water and stir for 20 minutes to reach full solubility.

The administration of the medicated drinking water should be repeated every 12 hours.

Do not administer the product through a dosing pump (proportioner).
Do not use a water acidifier simultaneously.
Do not use the product with water systems composed of metal.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 1 day

11. SPECIAL STORAGE PRECAUTIONS

Do not use after the expiry date stated on the label.
Shelf life after first opening the immediate packaging: 7 days.
Shelf life after dilution or reconstitution according to directions: 24 hours.
Once opened, use by: .....
Keep out of the sight and reach of children.
Store below 25 °C.
Keep the container tightly closed in order to protect from moisture.
Store in a dry place.

12. SPECIAL WARNINGS

Special precautions for use in animals:
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water animals should be treated parenterally.
Use of the product should be based on susceptibility testing and should take into account official national and regional policies with respect to the use of broad-spectrum antibiotics. Do not use in cases of bacteria susceptible to narrow spectrum penicillins or to amoxicillin as a single substance. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin and clavulanic acid, and may decrease the effectiveness of treatment with other beta-lactam antibiotics, due to the potential for cross resistance.
Due to the resistance rate detected in porcine *E. coli* isolates to amoxicillin/clavulanic acid in some

countries, the product should be used for the treatment of infections caused by *E. coli* only after susceptibility testing has been carried out. Administration of the product should not be used as a method to control non-clinical *Salmonella* infections in pig herds. It is strictly recommended, that the product should not be used as a tool of *Salmonella* control programmes.
In the case of a history of MRSA on a farm it is inappropriate to use a combination of amoxicillin and clavulanic acid as there is a likelihood to co-select for MRSA.
The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.

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 reactions 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 great care to avoid exposure, taking all recommended precautions.
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.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143.
Wear gloves during preparation and administration of medicated water.
Wash any exposed skin after handling the product or medicated water.
Wash hands after use.

Pregnancy and lactation:
Laboratory studies in rats and mice have not produced any evidence of mutagenicity, teratogenic and foetotoxic effects.
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:
In general, penicillins may be inhibited by the antibiotics with bacteriostatic action such as macrolides, sulfonamides and tetracyclines. No specific data on interaction of the combination have been described in the veterinary literature available. Neomycin given orally inhibits the intestinal absorption of penicillin.
Penicillins may increase the effect of aminoglycosides.

Overdose:
In case of severe hypersensitive reactions, the treatment should be discontinued and corticosteroids and adrenaline should be administered. Treatment should be symptomatic in other cases of adverse reactions.

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products

should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Country specific information

15. OTHER INFORMATION