B. PACKAGE LEAFLET

PACKAGE LEAFLET

NICILAN 400 mg/100 mg tablets for dogs

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

Laboratorios Calier, S.A.
Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès (Barcelona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NICILAN 400 mg/100 mg tablets for dogs

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

Each tablet contains:
Active substances:
Amoxicillin (as trihydrate) ..... 400 mg
Clavulanic acid (as potassium clavulanate) ..... .100 mg

Excipients:
Erythrosine (E-127) 7.5mg

Uniform pink oblong divisible tablet

4. INDICATION(S)

The product is indicated in dogs and cats for the treatment of bacterial infections caused by beta-lactamase producing strains resistant to amoxicillin and sensitive to amoxicillin/clavulanic acid:

- Infections of the respiratory tract (*Streptococcus spp*., *Staphylococcus spp*., *Pasteurella spp*.)
- Infections of the genitourinary tract (*Streptococcus spp*., *Staphylococcus spp*., *Escherichia coli, Fusobacterium spp.*)
- Infections of the digestive tract (*Escherichia coli* and *Proteus spp.*)
- Infections of the skin and soft tissues (*Staphylococcus spp.*, *Streptococcus spp*.)

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to penicillins, to other beta-lactams or to any of the excipients.
Do not use in rabbits, guinea pigs, hamsters, gerbils and chinchillas.
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria and/or oliguria.
Do not use where resistance to this combination is known to occur.

6. ADVERSE REACTIONS

In very rare cases it has been observed:

- Digestive tract disorders as diarrhoea, vomiting and colitis
- Allergic reactions which severity may vary from urticaria to anaphylaxia. If allergic reactions occur, medication should be discontinued and symptomatic treatment should be administered.
- Blood dyscrasies
- Secondary infections by non sensitive micro-organisms after a prolonged use.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals).
- Rare (more than 1 but less than 10 animals in 10,000 animals).
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

- Treatment may be discontinued depending on the severity of the undesirable effects and a benefit/risk evaluation by the veterinary surgeon.

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

7. TARGET SPECIES

Dogs

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

Oral use.
The dose is 10 mg amoxicillin + 2.5 mg clavulanic acid / kg body weight twice daily. The following table is intended as a guide to dispensing the product at this standard dose rate:

Body weight (kg)	Number of tablets twice daily
20	½
40	1
More than 40	1-1/2

Duration of treatment:
It not is recommended to extend treatment beyond 5 - 7 days.
According to veterinary criteria, dosage and frequency of administration can be increased.

9. ADVICE ON CORRECT ADMINISTRATION

To minimise gastrointestinal effects, it is recommended to administer the product at the beginning of meals. Tablets may be added to food.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Tablets may be added to food.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 30°C.

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

12. SPECIAL WARNING(S)

Special precautions for use in animals

In animals with hepatic or renal dysfunction, the dosing regimen should be carefully evaluated and the use of the product based on a risk/benefit evaluation by the veterinary surgeon. Caution is advised in the use in small herbivores other than those in the section 4.3.
Whenever possible, the antimicrobial should only be used based on susceptibility testing.
Do not use in case of bacteria sensitive to narrow-spectrum penicillins or amoxicillin as single substance.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin/clavulanic acid and may decrease the effectiveness of treatment with beta-lactam antibiotics, due to the potential for crossresistance.
The potential for allergic cross-reactions with other penicillins and cephalosporins should be considered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillins and cephalosporins can cause hipersensitivity reactions (allergy) after injection, inhalation, ingestion or skin contact. Hipersensitivity to pencillins may lead to cross-reactions to cephalosporins and viceversa. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity to penicillins and/or cephalosporins should avoid contact with the veterinary medicinal product.

Avoid direct contact with the veterinary medicine by taking specific precautions:
- Wash hands after handling the veterinary medicine
- Do not smoke, eat or drink while handling the veterinary medicine

If symptoms such as skin rash occur after accidental exposure, seek medical advice and show the package leaflet or the label to the physician. Swelling of face, lips or

eyes or difficulty with breathing are more serious symptoms that require urgent medical attention.

Use during pregnancy and lactation
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.
Use only according to the benefit/risk assessment by the veterinary responsible.
Studies in laboratory animals have not shown any evidence of teratogenic effects.

Interaction with other medicinal products and other forms of interaction:
Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatical action.

Penicillins may increase the effect of aminoglycosides.

Overdose (symptoms, emergency procedures, antidotes):
In case of overdose, gastrointestinal signs (diarrhoea, vomiting) and/or allergic reactions could appear. Symptomatic treatment should be initiated when necessary.

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 product should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2007

15. OTHER INFORMATION

Blister of polyamide aluminium /PVC and lake thermosolderable aluminium foils containing 6 tablets
Pack sizes:

carton box containing 12 tablets (2 blisters)
carton box containing 60 tablets (10 blisters)
carton box containing 120 tablets (20 blisters)
carton box containing 240 tablets (40 blisters)

Not all pack sizes may be marketed.