

ANNEX III
LABELLING AND PACKAGE LEAFLET

B. PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clavubay 200 mg / 50 mg Tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Amoxicillin	200 mg
(as amoxicillin trihydrate)	229.5 mg
Clavulanic acid	50 mg
(as potassium clavulanate)	59.5 mg

Excipient:

Carmoisine Lake (E122)	1.225 mg
------------------------	----------

Round pink tablet with a score line and 250 embossed on opposing faces.

3. Target species

Dogs.

4. Indications for use

For the treatment of the following infections caused by β -lactamase producing strains of bacteria sensitive to amoxicillin in combination with clavulanic acid:

- Skin infections (including superficial and deep pyodermas) caused by susceptible Staphylococci.
- Urinary tract infections caused by susceptible Staphylococci or Escherichia coli.
- Respiratory infections caused by susceptible Staphylococci.
- Enteritis caused by susceptible Escherichia coli.

It is recommended to carry out suitable tests for sensitivity testing when initiating the treatment. The treatment should only proceed if sensitivity is proven to the combination.

5. Contraindications

Do not use in rabbits, guinea pigs, hamsters or gerbils.

Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group.

Do not use in animals with serious dysfunction of the kidneys accompanied by anuria and oliguria.

Do not use where resistance to this combination is known to occur.

Do not administer to horses and ruminating animals.

6. Special warnings

Special precautions for safe use in the target species:

Inappropriate use of the product may increase the prevalence of bacteria resistant to amoxicillin/clavulanic acid.

In animals with hepatic and renal failure, the dosing regimen should be carefully evaluated.

Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies. Narrow spectrum antibacterial therapy should be used for first line treatment where susceptibility testing suggests likely efficacy of this approach.

Do not administer to horses and ruminating animals.

Caution is advised in the use in small herbivores other than those reported in contradictions.

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 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 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 package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Pregnancy:

Studies in laboratory animals have not produced any evidence of teratogenic effects. Use only according to the benefit-risk assessment by the responsible veterinarian during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

The potential for allergic cross-reactivity with other penicillins should be considered. Penicillins may increase the effect of aminoglycosides.

Chloramphenicol, macrolides, sulphonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action.

Overdose:

The veterinary medicinal product is of a low order of toxicity and is well tolerated by the oral route. In a tolerance study a tested dose of 3 times the recommended dose of 12.5 mg of the combined actives administered twice daily for 8 days did not demonstrate adverse reactions.

<Special restrictions for use and special conditions for use:>

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal disorders (Diarrhoea, Vomiting) Allergic reactions (e.g. skin reaction, anaphylaxis) ¹ Hypersensitivity reaction ²
---	---

¹ In these cases, treatment should be withdrawn.

² Unrelated to dose

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

Dosage Rate: 12.5 mg combined actives/kg bodyweight twice daily. The recommended dose of 12.5 mg per kg bodyweight is equivalent to one 250 mg tablet per 20 kg bodyweight.

Dosage frequency: The following tables are intended as a guide to dispensing the veterinary medicinal product at the standard dose rate of 12.5 mg/kg twice daily.

Bodyweight (kg)	Number of tablets per dose twice daily
	250 mg
19-20	●
21-30	● ◐
31-40	● ●
41-50	● ● ◐
more than 50	● ● ●

Duration of therapy: Routine cases involving all indications: The majority of cases respond to between 5 and 7 days therapy.

Chronic or refractory cases: In these cases where there is considerable tissue damage, a longer course of therapy may be required in that it allows sufficient time for damaged tissue to repair.

9. Advice on correct administration

Oral use. The tablets may be crushed and added to a little food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Store in the original package in order to protect from moisture.

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

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Package sizes:

HDPE box with 100 tablets

HDPE box with 250 tablets

Cardboard box with 4 blisters (20 tablets)

Cardboard box with 10 blisters (50 tablets)

Cardboard box with 20 blisters (100 tablets)

Cardboard box with 50 blisters (250 tablets)

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer responsible for batch release:

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan
Ireland

Local representatives and contact details to report suspected adverse events:

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

17. Other information

Resistance to many antibiotics is caused by beta-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanate in Noroclav Tablets counteracts this defence mechanism by inactivating the beta-lactamases, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the body.

In vitro potentiated amoxicillin is active against a wide range of clinically important aerobic and anaerobic bacteria including:

Gram-positive:

Staphylococci (including β -lactamase producing strains)

Clostridia

Streptococci

Gram-negative:

Escherichia coli (including most β -lactamase producing strains)

Campylobacter spp

Pasteurellae

Proteus spp

Resistance is shown among *Enterobacter* spp, *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus*. A trend in resistance of *E. coli* is reported.