1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 50 mg Tablets for Dogs and Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Amoxicillin (as amoxicillin trihydrate) 40 mg
Clavulanic acid (as potassium clavulanate) 10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Carmoisine Lake (E122)	0.245 mg
Sodium Starch Glycollate	
Copovidone	
Magnesium Stearate	
Microcrystalline Cellulose	
Calcium Carbonate	
Silicon Dioxide	
Heavy Magnesium carbonate	
Roast Beef Flav-o-lok	

Round pink tablet with a score line and 50 embossed on opposing faces.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in cases of hypersensitivity to penicillin, other substances of the beta-lactam group or to any of the excipients.
Do not use in rabbits, guinea pigs, hamsters or gerbils.
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.

3.4 Special warnings

None.

3.5 Special precautions for use

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 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.
Caution is advised in the use in small herbivores other than those in 3.3.
Dogs and cats diagnosed with *Pseudomonas* infections should not be treated with this antibiotic combination.

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 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal disorders (Diarrhoea, Vomiting) Allergic reactions (e.g. skin reaction, anaphylaxis) [1] Hypersensitivity reactions[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Laboratory studies in dogs and cats have not produced any evidence of teratogenic effects. Use only according to the benefit/risk assessment by the responsible veterinarian.

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

3.9 Administration routes and dosage

Oral use. The dosage rate is 12.5 mg combined actives/kg bodyweight twice daily. The tablets may be crushed and added to a little food.

The following table is intended as a guide to dispensing the product at the standard dose rate of 12.5 mg of combined actives per kg twice daily.

Bodyweight	Number of tablets twice daily
1-2	0.5
3-4	1
5-6	1.5
7-8	2
9-10	2.5
11-12	3
13-14	3.5
15-16	4
17-18	4.5

Duration of therapy
Acute cases: 5 to 7 days of treatment.
If no improvement is observed after 5 to 7 days, the diagnosis should be re-assessed.
Chronic or refractory cases: In these cases where there is considerable tissue damage, a longer course of therapy may be required so that it allows sufficient time for damaged tissue to repair.
If no improvement is observed after two weeks, the diagnosis should be re-assessed.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The veterinary medicinal product is of a low order of toxicity and is well tolerated by the oral route.
In a tolerance study in dogs a tested dose of 3 times the recommended dose of 12.5 mg of the combined actives administered twice daily during 8 days did not demonstrate adverse effects.
In a tolerance study in cats a tested dose of 3 times the recommended dose of 12.5 mg of the combined actives administered twice daily during 15 days did not demonstrate adverse effects.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CR02

4.2 Pharmacodynamics

Amoxicillin is a beta-lactam antibiotic and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins. Amoxicillin shows activity against susceptible Gram-positive bacteria and Gram-negative bacteria.
Beta-lactam antibiotics prevent the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis of growing cells only.
Clavulanic acid is one of the naturally occurring metabolites of the streptomycete *Streptomyces clavuligerus.* It has a structural similarity to the penicillin nucleus, including possession of a beta-lactam ring. Clavulanic acid is a betalactamase inhibitor acting initially competitively but ultimately irreversibly. Clavulanic acid will penetrate the bacterial cell wall binding to both extracellular and intracellular beta-lactamases.
Amoxicillin is susceptible to breakdown by β-lactamase and therefore combination with an effective ß-lactamase inhibitor (clavulanic acid) extends the range of bacteria against which it is active to include ß-lactamase producing species.

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.

4.3 Pharmacokinetics

Amoxicillin is well-absorbed following oral administration. In dogs the systemic bioavailability is 60-70%.
Amoxicillin (pKa 2.8) has a relatively small apparent distribution volume, a low plasma protein binding (34% in dogs) and a short terminal half-life due to active tubular excretion via the kidneys. Following absorption the highest concentrations are found in the kidneys (urine) and the bile and then

in liver, lungs, heart and spleen. The distribution of amoxicillin to the cerebrospinal fluid is low unless the meninges are inflamed.
Clavulanic acid (pK1 2.7) is also well-absorbed following oral administration. The penetration to the cerebrospinal fluid is poor. The plasma protein binding is approximately 25% and the elimination half-life is short. Clavulanic acid is heavily eliminated by renal excretion (unchanged in urine).
After oral administration of the recommended dose of 12.5 mg combined actives/kg to dogs, the following parameters were observed: C_{max} of 6.30 +/-0.45 µg/ml, T_{max} of 1.98 +/- 0.135 hours and AUC of 23.38 +/- 1.39 µg/ml.hr for amoxicillin and C_{max} of 0.87 +/- 0.1 µg/ml, T_{max} of 1.57 +/- 0.177 hours and AUC of 1.56 +/- 0.24 microg/ml.hr for clavulanic acid.
After oral administration of the recommended dose of 12.5 mg combined actives/kg to cats, the following parameters were observed: C_{max} of 7.12 +/-1.460 µg/ml, T_{max} of 2.69 +/- 0.561 hours and AUC of 33.54 +/- 7.335 µg/ml.hr for amoxicillin and C_{max} of 1.67 +/- 0.381 µg/ml, T_{max} of 1.83 +/- 0.227 hours and AUC of 7.03 +/- 1.493 µg/ml.hr for clavulanic acid.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year (blister packs), 6 months (tubs).

5.3 Special precautions for storage

Do not store above 25 °C.
Store in the original package in order to protect from moisture.

5.4 Nature and composition of immediate packaging

The product is supplied in high-density polyethylene tubs with a polypropylene screw cap lid containing 100 tablets and in high-density polyethylene tubs with a polyethylene screw cap lid containing 500 tablets. A sachet of desiccant is included in each container. The product is also presented in packs containing 2, 10 and 50 blister strips (aluminium-aluminium) each containing 10 tablets per strip.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/072/001

8. DATE OF FIRST AUTHORISATION

25 April 2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

31 January 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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