

FOR ANIMAL TREATMENT ONLY
RESTRICTED VETERINARY MEDICINE
Highly Important Antibiotics

Noroclav Tablets 500 mg

PRESENTATIONS

Noroclav Tablets 500 mg are presented as beef flavoured, pink circular tablets.
Each tablet contains 400 mg AMOXICILLIN as amoxicillin trihydrate
100 mg CLAVULANIC ACID as potassium clavulanate

Tablets are available in packs of 100.

PRODUCT SUMMARY

- Dual action of clavulanic acid and amoxicillin
- Extended spectrum of activity - clavulanate extends the spectrum of amoxicillin by making it active against resistant (β -lactamase producing) strains of *Staphylococcus* spp and *E. coli*, as well as to the list of susceptible organisms.
- Rapid bactericidal action – increases the likelihood of a rapid clinical cure.
- Excellent absorption and penetration.
- Easy to administer.
- Convenient twice daily dosage.
- Absorption not significantly affected by food.

MODE OF ACTION

Resistance to many antibiotics is caused by β -lactamase enzymes produced by bacteria, which destroy the antibiotic before it can act on those bacteria. The clavulanate in Noroclav Tablets 500 mg counteracts this defence mechanism by inactivating the β -lactamases, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.

INDICATIONS

For the treatment of bacterial infections sensitive to clavulanic acid and amoxicillin in pre-ruminant calves and dogs. This antibiotic combination is active *in vitro* against a wide range of clinically important aerobic and anaerobic bacteria including:

Gram-positive: *Staphylococcus* spp (including β -lactamase producing strains); *Corynebacterium* spp; *Streptococcus* spp, *Bacillus* spp, *Erysipelas* spp, *Clostridium* spp.

Gram-negative: *Bacteroides* spp (including β -lactamase producing strains); *Escherichia coli* (including most β -lactamase producing strains); *Bordetella bronchiseptica*; *Pasteurella* spp, *Proteus* spp, *Fusobacterium* spp, *Brucella* spp, *Haemophilus* spp, *Moraxella* spp.

Not indicated for cases involving *Pseudomonas* and *Klebsiella* spp.

Clinically amoxicillin/clavulanic acid has been shown to be effective in treating a wide range of diseases of dogs including: Skin disease (including deep and superficial pyodermas); soft tissue infections (abscesses and anal sacculitis); dental infections (e.g. gingivitis); urinary tract infections; respiratory disease (involving upper and lower respiratory tract); enteritis. In calves, amoxicillin/clavulanic acid has been shown to be effective in treating bacterial respiratory infections and enteritis.

CONTRAINDICATIONS

Contra-indicated in known cases of hypersensitivity to penicillins. Do not administer to small herbivores e.g. guinea pigs.

ADMINISTRATION & DOSAGE

Calves

For oral administration only

The standard dose rate is 12.5mg/kg bodyweight (provided by one 500mg tablet per 40kg) twice daily within the recommended dose range of 7-15mg/kg bodyweight of combined amoxicillin and clavulanic acid. Use a dose rate as directed depending on the severity of the case. Treatment should be continued until 12 hours after all symptoms have subsided or as directed by your veterinarian.

For example: a 40 kg calf will require one tablet twice daily.

Any variation by the prescribing veterinarian to the approved dose, frequency, duration, route, disease or target species may result in the need to extend the approved withholding period.

Amoxicillin given orally is inactivated in calves that have a functional rumen (i.e. from 6 weeks of age, if fed herbage or concentrates).

Dogs

For oral administration only. The recommended dose rate is 12.5 mg of combined active ingredients per kilogram bodyweight, twice daily. The following table is a guide to dispensing Noroclav Tablets 500 mg at the standard dose rate:

Bodyweight (kg) of dog	Number of 500 mg tablets per dose, twice daily
20 kg	1/2
40 kg	1
60 kg	1 1/2
80 kg	2

DURATION OF THERAPY

Routine cases involving all indications:

Therapy should be continued for 5-7 days, or for 48 hours after all symptoms have subsided.

Chronic or refractory cases:

In these cases, where there is considerable tissue damage, a longer course of therapy may be required to allow sufficient time for damaged tissue to repair. Based on clinical trials, the following durations are suggested as guideline:

Chronic skin disease	10-20 days
Chronic cystitis	10-28 days
Respiratory disease	8-10 days

PRUDENT USE STATEMENT

Potentiated Penicillin (Amoxycillin and Clavulanic Acid) is an antibiotic in the penicillin family and is considered highly important to human and animal health. The use of this antibiotic should only be for the minimum period needed to meet the clinical objective. Clinical response to this antibiotic should be monitored during treatment, and choice of therapy reviewed if clinical signs of disease persist, increase, or relapse. In the event of treatment failure, culture and sensitivity should be considered to determine an appropriate alternative therapy. Indiscriminate use of this antibiotic can contribute to the development of antibiotic resistance.

WITHHOLDING PERIOD

It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds.

MEAT: Calves producing meat or offal for human consumption must not be sold for slaughter either during treatment or within **4 days** of the last treatment.

NOT FOR USE in bobby calves

Handling Precautions:

Repeated exposure to amoxicillin trihydrate may cause skin allergy.

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 skin contact.

First Aid:

If you develop symptoms following exposure such as skin rash you should seek medical advice and show the doctor this package or insert. Swelling of the face, eyes or lips or difficulty with breathing are more serious symptoms and require urgent medical attention.

Disposal:

Preferably dispose of product by use. Otherwise dispose of product, packaging and waste at an approved landfill or equivalent facility.

KEEP OUT OF REACH OF CHILDREN.

Store below 25°C (Room temperature), in a dry place.

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See www.foodsafety.govt.nz for registration conditions.

Registered to & distributed by:

Norbrook NZ Ltd

KPMG Centre, 18 Viaduct Harbour Avenue

Auckland

Ph: 0800 224 022

Manufactured by:

Norbrook Laboratories Ltd.

Station Works,

NEWRY,

Co. Down,

Northern Ireland.