

Synuclav[®]

50 mg tablets for Dogs and Cats

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

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

STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Amoxicillin (as amoxicillin trihydrate)	40 mg
Clavulanic acid (as potassium clavulanate)	10 mg
Carmoisine Lake (E122)	0.245 mg

INDICATIONS

Synuclav 50 mg tablets are indicated for 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.

CONTRAINDICATIONS

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

ADVERSE REACTIONS

Hypersensitivity reactions unrelated to dose can occur with these agents. Gastrointestinal symptoms (diarrhoea, vomiting) may occur after administration of the product. Allergic reactions (e.g. skin reactions, anaphylaxis) may occasionally occur. In case of

occurrence of allergic reaction, the treatment should be withdrawn. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

TARGET SPECIES

Dogs and cats.

DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

12.5 mg combined actives/kg bodyweight twice daily. The recommended dose of 12.5 mg per kg bodyweight is equivalent to one 50 mg tablet per 4 kg bodyweight.

Dosage frequency:

The following table is intended as a guide to dispensing Synuclav 50mg Tablets at the standard dose rate of 12.5 mg/kg twice daily.

Bodyweight (kg)	50mg	Number of tablets per dose twice daily
1-2	●	
3-4	●●	
5-6	●●●	
7-8	●●●●	=====
9-10	●●●●●	=====
11-12	●●●●●●	=====
13-14	●●●●●●●	=====
15-16	●●●●●●●●	=====
17-18	●●●●●●●●●	=====

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.

ADVICE ON CORRECT ADMINISTRATION

By the oral route. The tablets may be crushed and added to a little food.

WITHDRAWAL PERIOD

Not applicable

SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in the original package in order to protect from moisture. Do not use after the expiry date stated on the blister or tubs. Keep out of the sight and reach of children. Keep the container in the outer carton.

SPECIAL WARNINGS

Inappropriate use of the product may increase the prevalence of bacteria resistance 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.

Dogs and cats diagnosed with *Pseudomonas* infections should not be treated with this antibiotic combination.

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

The potential for allergic cross-reactivity with other penicillins should be considered.

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

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

Penicillins may increase the effect of aminoglycosides.

Operator warnings:

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. Wash hands after use.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED.

October 2015

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 Synuclav 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

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.

Vm: 02000/4224

ManA 2000

DISTRIBUTED BY:

MiGroup

12b Progress Way

Mid Suffolk Business Park

Eye

Suffolk

IP23 7HU

United Kingdom