BETACILIN CLAV- amoxicillin and clavulanate potassium tablet, coated MWI Animal Health

Betacillin Clav™ Tablets (Amoxicillin and Clavulanate Potassium Tablets)

Veterinary Tablets For use in dogs and cats

CAUTION:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:

Betacilin Clav Tablets are an orally administered formulation comprised of the broadspectrum antibiotic amoxicillin trihydrate and the β -lactamase inhibitor, clavulanate potassium (the potassium salt of clavulanic acid).

Amoxicillin trihydrate is a semisynthetic antibiotic with a broad spectrum of bactericidal activity against many gram-positive and gram-negative, aerobic and anaerobic microorganisms. It does not resist destruction by β -lactamases; therefore, it is not effective against β -lactamase producing bacteria. Chemically, it is D (-)- α -amino-p-hydroxybenzyl penicillin trihydrate.

Clavulanic acid, an inhibitor of β-lactamase enzymes, is produced by the fermentation of *Streptomyces clavuligerus*. Clavulanic acid by itself has only weak antibacterial activity. Chemically, clavulanate potassium is potassium z-(3R,5R)-2-β-hydroxyethylidene clavam-3-carboxylate.

ACTIONS:

Betacilin Clav Tablets are stable in the presence of gastric acid and are not significantly influenced by gastric or intestinal contents. The 2 components are rapidly absorbed resulting in amoxicillin and clavulanic acid concentrations in serum, urine, and tissues similar to those produced when each is administered alone.

Amoxicillin and clavulanic acid diffuse readily into most body tissues and fluids with the exception of brain and spinal fluid, which amoxicillin penetrates adequately when meninges are inflamed. Most of the amoxicillin is excreted unchanged in the urine. Clavulanic acid's penetration into spinal fluid is unknown at this time. Approximately 15% of the administered dose of clavulanic acid is excreted in the urine within the first 6 hours.

Betacilin Clav Tablets combine the distinctive properties of a broad-spectrum antibiotic and a β -lactamase inhibitor to effectively extend the antibacterial spectrum of amoxicillin to include β -lactamase producing as well as non- β -lactamase-producing aerobic and anaerobic organisms.

MICROBIOLOGY:

Amoxicillin is bactericidal in action and acts through the inhibition of biosynthesis of cell wall mucopeptide of susceptible organisms. The action of clavulanic acid extends the antimicrobial spectrum of amoxicillin to include organisms resistant to amoxicillin and other β -lactam antibiotics. Amoxicillin/clavulanate has been shown to have a wide range of activity which includes β -lactamase producing strains of both gram-positive and gram-negative aerobes, facultative anaerobes, and obligate anaerobes. Many strains of the following organisms, including β -lactamase-producing strains, isolated from veterinary sources, were found to be susceptible to amoxicillin/ clavulanate *in vitro* but the clinical significance of this activity has not been demonstrated for some of these organisms in animals.

Aerobic bacteria, including *Staphylococcus aureus*¹, β-lactamase producing *Staphylococcus aureus*¹ (penicillin resistant), *Staphylococcus* species¹, *Staphylococcus epidermidis, Staphylococcus intermedius, Streptococcus faecalis, Streptococcus* species¹, *Corynebacterium pyogenes, Corynebacterium* species, *Erysipelothrix rhusiopathiae, Bordetella bronchiseptica, Escherichia coli*¹, *Proteus mirabilis, Proteus* species, *Enterobacter* species, *Klebsiella pneumoniae, Salmonella dublin, Salmonella typhimurium, Pasteurella multocida, Pasteurella haemolytica, Pasteurella* species¹

¹ The susceptibility of these organisms has also been demonstrated in *in vivo* studies.

Studies have demonstrated that both aerobic and anaerobic flora are isolated from gingival cultures of dogs with clinical evidence of peridontal disease. Both gram-positive and gram-negative aerobic and anaerobic subgingival isolates indicate sensitivity to amoxicillin/clavulanic acid during antimicrobial susceptibility testing.

SUSCEPTIBILITY TEST:

The recommended quantitative disc susceptibility method (FEDERAL REGISTER 37:20527-29; Bauer AW, KirbyWMM, Sherris JC, *et al*: Antibiotic susceptibility testing by standardized single disc method. *Am J Clin Path* 45:493, 1966) utilized 30 mcg Augmentin® (AMC) discs for estimating the susceptibility of bacteria to amoxicillin and clavulanate potassium tablets.

INDICATIONS:

Betacilin Clav Tablets are indicated in the treatment of:

Dogs: Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: β-lactamase-producing *Staphylococcus aureus*, non-β-lactamase-producing *Staphylococcus aureus*, Staphylococcus spp., *Streptococcus spp.*, and *E. coli*.

Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria. Betacilin Clav Tablets have been shown to be clinically effective for treating cases of canine periodontal disease. *Cats:* Skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms:

β-lactamase-producing *Staphylococcus aureus*, non-β-lactamase producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E.coli*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

Therapy may be initiated with Betacilin Clav Tablets prior to obtaining results from bacteriological and susceptibility studies. A culture should be obtained prior to treatment to determine susceptibility of the organisms to Betacilin Clav Tablets. Following determination of susceptibility results and clinical response to medication, therapy may be reevaluated.

CONTRAINDICATIONS:

The use of this drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins or cephalosporins.

WARNINGS:

Safety of use in pregnant or breeding animals has not been determined. Store at controlled room temperature, 68-77°F (20-25°C).

Do not remove from foil strip until ready to use.

Keep Betacilin Clav Tablets in a secure location out of reach of dogs, cats and other animals to prevent accidental ingestion or overdose.

ADVERSE REACTIONS:

Betacilin Clav Tablets contain a semisynthetic penicillin (amoxicillin) and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids.

Post-Approval Experience (July, 2017):

The following adverse events are based on the post-approval adverse drug experience reporting. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a casual relationship to product exposure using these data.

The following adverse events reported for dogs and cats are listed in decreasing order of reporting frequency for amoxicillin and clavulanate potassium tablets: Anorexia, lethargy, vomiting and diarrhea.

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Cronus Pharma LLC at 1-844-227- 6687 (1-844-2-CRONUS). For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

DOSAGE AND ADMINISTRATION:

Dogs: The recommended dosage is 6.25 mg/lb of body weight twice a day.

Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyoderma, and periodontal infections should be treated for 5-7 days or for 48 hours after all symptoms have subsided. If no response is seen after 5 days of treatment, therapy should be discontinued and the case reevaluated.

Deep pyoderma may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

Cats: The recommended dosage is 62.5 mg twice a day.

Skin and soft tissue infections such as abscesses and cellulitis/dermatitis should be treated for 5-7 days or for 48 hours after all symptoms have subsided, not to exceed 30 days. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated.

Urinary tract infections may require treatment for 10-14 days or longer. The maximum duration of treatment should not exceed 30 days.

HOW SUPPLIED:

Betacilin Clav Tablets in the following strengths are supplied in strip packs. Each carton holds 15 strips with 14 tablets per strip (210 tablets per carton).

Each 62.5-mg tablet contains amoxicillin trihydrate equivalent to 50 mg of amoxicillin activity and 12.5 mg of clavulanic acid as the potassium salt. For use in dogs and cats.

Each 125-mg tablet contains amoxicillin trihydrate equivalent to 100 mg of amoxicillin activity and 25 mg of clavulanic acid as the potassium salt. For use in dogs only.

Each 250-mg tablet contains amoxicillin trihydrate equivalent to 200 mg of amoxicillin activity and 50 mg of clavulanic acid as the potassium salt. For use in dogs only.

Each 375-mg tablet contains amoxicillin trihydrate equivalent to 300 mg of amoxicillin activity and 75 mg of clavulanic acid as the potassium salt. For use in dogs only.

Dispense according to recommendations outlined in Dosage and Administration section.

Augmentin is a trademark owned by GlaxoSmithKline.

Approved by FDA under ANADA # 200-702

Distributed by: MWI Boise, ID 83705 www.VetOne.net Contact No: 1-844-227-6687 (1-844-2-CRONUS)

Made in India

Rev. 02/2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 86136-001-21

VET one[®]

Betacilin Clav™ Tablets

(Amoxicillin and Clavulanate Potassium Tablets)

62.5 mg

Veterinary Tablets

For use in dogs and cats

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

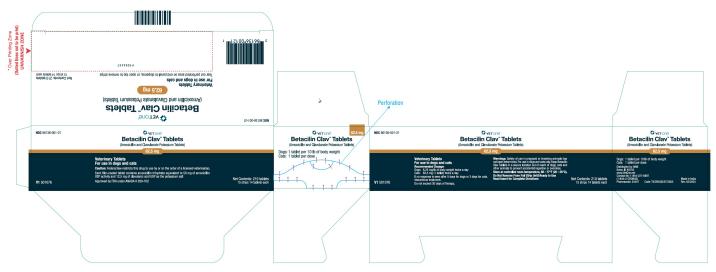
Each film-coated tablet contains amoxicillin trihydrate equivalent to 50 mg of amoxicillin USP activity and 12.5 mg of clavulanic acid USP as the potassium salt

Approved by FDA under ANADA # 200-702

V1 501076

Net Contents: 210 tablets

15 strips 14 tablets each



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 86136-002-21

 $\mathsf{VET}\,\mathsf{one}^{\mathbb{R}}$

Betacilin Clav™ Tablets

(Amoxicillin and Clavulanate Potassium Tablets)

125 mg

Veterinary Tablets

For use in dogs

C**aution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

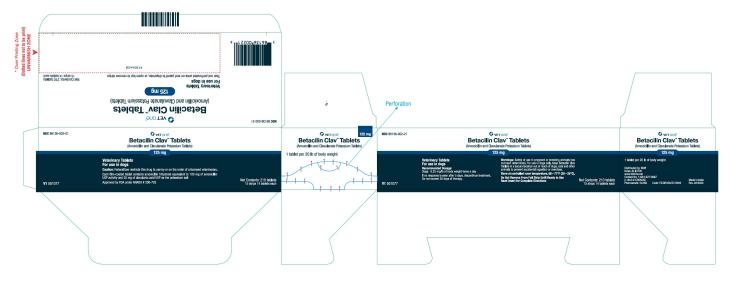
Each film-coated tablet contains amoxicillin trihydrate equivalent to 100 mg of amoxicillin USP activity and 25 mg of clavulanic acid USP as the potassium salt

Approved by FDA under ANADA # 200-702

V1 501077

Net Contents: 210 tablets

15 strips 14 tablets each



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 86136-003-21

 $\mathsf{VET}\,\mathsf{one}^{\mathbb{R}}$

Betacilin Clav™ Tablets

(Amoxicillin and Clavulanate Potassium Tablets)

250 mg

Veterinary Tablets

For use in dogs

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

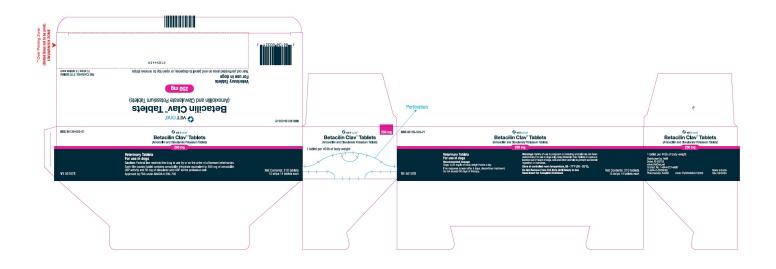
Each film-coated tablet contains amoxicillin trihydrate equivalent to 200 mg of amoxicillin USP activity and 50 mg of clavulanic acid USP as the potassium salt

Approved by FDA under ANADA # 200-702

V1 501078

Net Contents: 210 tablets

15 strips 14 tablets each



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 86136-004-21

 $\mathsf{VET}\,\mathsf{one}^{\mathbb{R}}$

Betacilin Clav™ Tablets

(Amoxicillin and Clavulanate Potassium Tablets)

375 mg

Veterinary Tablets

For use in dogs

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

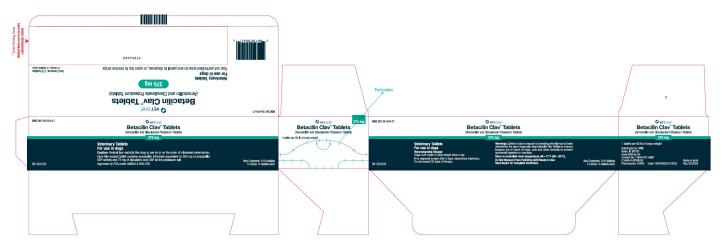
Each film-coated tablet contains amoxicillin trihydrate equivalent to 300 mg of amoxicillin USP activity and 75 mg of clavulanic acid USP as the potassium salt

Approved by FDA under ANADA # 200-702

V1 501079

Net Contents: 210 tablets

15 strips 14 tablets each



BETACILIN CLAV

amoxicillin and clavulanate potassium tablet, coated

Product Inform								
Product Type	PRESCRIPTI	ION ANIMA	L DRUG	Item Code	e (Source)	NDC:8	6136-001	
Route of Administ	tration	ORAL						
Active Ingredie		-						
	redient Name				Basis of S	Strength	Strengt	
AMOXICILLIN (UNII: 8	804826J2HU)	(AMOXICILLIN	ANHYDRC	OUS - UNII:9E	M05410Q9)	AMOXICILLIN ANHYDROUS		50 mg
CLAVULANATE POTA UNII:23521W1S24)	ASSIUM (UNII	I: Q420MW3A	T8) (CLAV	ULANIC ACID	-	CLAVULANIC	ACID	12.5 mg
Product Charac	teristics							
Color	whi	te	Scor	е		n	o score	
Shape	ROL	JND	Size			6	mm	
Flavor			Impr	int Code				
Contains								
Contains								
Packaging								
Packaging # Item Code		ige Descri	ption	Marketin	ng Start Da	ate Mar	keting E	nd Date
Packaging # Item Code 1 NDC:86136-001-21	15 in 1 C/	ARTON		Marketin	ıg Start Da	ate Mar	keting E	nd Date
Packaging # Item Code 1 NDC:86136-001-21	15 in 1 C/	•		Marketin	ig Start Da	ate Mar	keting E	nd Date
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Packaging # Item Code 1 NDC:86136-001-21 1 Marketing Ir	15 in 1 C/ 14 in 1 BI	ARTON LISTER PACK Citat	er or Mo		Market	ing Start ate	Marke	nd Date ting End ate
Packaging # Item Code 1 NDC:86136-001-21 1 Marketing Ir Category	15 in 1 C/ 14 in 1 BI Iformat Applica	ARTON LISTER PACK Citat	er or Mo		Market	ing Start ate	Marke	ting End
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Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				

CLAVULANATE POTAS UNII:23521W1S24)	SIUM (UNII:	: Q420MW3AT8) ((CLAVULANIC ACID	-	CLAVU	JLANIC	C ACID	25 mg
Product Charact	eristics							
Color	whit	e	Score				no score	
Shape	ROU	IND	Size				9mm	
Flavor			Imprint Code					
Contains								
Packaging								
# Item Code	Packa	ge Descriptio	on Marketir	ng Start Da	ate	Ма	rketing E	nd Date
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1	14 in 1 BL	ISTER PACK						
Marketing In								
					ting Start Marketing I Date Date			
Marketing Category	Аррпсат	Citation			-			ate
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Category ANADA BETACILIN CL amoxicillin and clavu Product Informa Product Type Route of Administr Active Ingredien AMOXICILLIN (UNII: 80 CLAVULANATE POTAS UNII:23521W1S24) Product Charact	ANADA2007(AV Ilanate po ation ation t/Active Ingr 4826J2HU) (SSIUM (UNII)	Citation 02 tassium tablet PRESCRIPTION A ORAL Moiety redient Name AMOXICILLIN ANH 2 Q42OMW3AT8) (t, coated ANIMAL DRUG IYDROUS - UNII:9E (CLAVULANIC ACID	D 07/22/202	e (Sou Basi AMOX ANHYI	i s of Icilli Drous	Strength NDC:80	5136-003 Strengt 200 mg
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Packaging									
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1		14 in 1 E	LISTER PACK						
Marketin _{Marketin}	-			or M	onograph	Market	ing Star	t Marke	ting End
Categor	y	Application Number or Monograph Citation				D	ate		ate
ANADA	4	ANADA200	702			07/22/202	1		
BETACILI	N CL/	٩V							
moxicillin and	d clavul	anate p	otassium tablet	t, co	ated				
Product In	forma	tion							
Product Type	e		PRESCRIPTION	ANIMA	AL DRUG	ltem Code	e (Source	e) NDC:8	6136-004
Route of Adı	ninistra	ation	ORAL						
Active Ingr	edient	:/Active	Moietv						
			redient Name	2			Basis o	f Strength	Strenat
	UNII: 804		(AMOXICILLIN ANF		DUS - UNII:9EM	l05410Q9)	AMOXICILI ANHYDRO	LIN	300 mg
CLAVULANATE UNII:23521W1S2		SIUM (UN	II: Q42OMW3AT8)	(CLA\	/ULANIC ACID -		CLAVULAN	IIC ACID	75 mg
Product Ch		rictica							
Color	aracu			Sco	r 0			no score	
Shape				Size	-			13mm	
Flavor		NC.			, rint Code			1311111	
Contains				mp					
Packaging									
# Item C			age Descriptio	on	Marketing	g Start Da	ate M	arketing E	nd Date
1 NDC:86136-0	004-21	15 in 1 C							
1		14 IN 1 E	LISTER PACK						
Marketin	a Inf	orma	tion						
Marketin Categor	g		ation Number o Citation		onograph		ing Stari ate		ting End ate
ANADA	-	NADA200	702			07/22/202	1		
ANADA									

Registrant - Cronus Pharma Specialities India Private Limited (876818318)

Establishment					
Name		Address	ID/FE	El	Business Operations
Apitoria Pharma Private Limited			918917634	4	api manufacture
Establishment					
Name	Addre	ss	ID/FEI		Business Operations
Fermic, S.A. de C.V.		81000	1040	api m	nanufacture
Establishment					
Name	A	ddress	ID/FEI		Business Operations

 Aurobindo Pharma Limited
 918917683
 analysis, manufacture

Revised: 5/2024

MW Animal Health