AMOXICILLIN AND CLAVULANATE POTASSIUM- amoxicillin and clavulanate potassium tablet, coated
Covetrus

Amoxicillin and clavulanate potassium 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: Amoxicillin and clavulanate potassium tablets are an orally administered formulation comprised of the broad-spectrum 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: Amoxicillin and clavulanate potassium 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.

Amoxicillin and clavulanate potassium 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* species[1], *Staphylococcus* epidermidis, *Staphylococcus intermedius*, *Streptococcus faecalis, Streptococcus* species[1], *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* species[1]

[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, Kirby WMM, 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: Amoxicillin and clavulanate potassium 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. Amoxicillin and clavulanate potassium 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 Amoxicillin and clavulanate potassium 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 Amoxicillin and Clavulanate Potassium 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

ADVERSE REACTIONS: Amoxicillin and clavulanate potassium 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 Covetrus at 1-855-724-3461. 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: Amoxicillin and clavulanate potassium 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

Questions?
(855) 724-3461
Distributed by:
Covetrus North America
400 Metro Place North
Dublin, OH 43017
covetrus.com
Made in India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 11695-6991-1

Amoxicillin and clavulanate potassium tablets

62.5 mg

For use in dogs and cats

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

210 tablets (15 strips, 14 tablets each)

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

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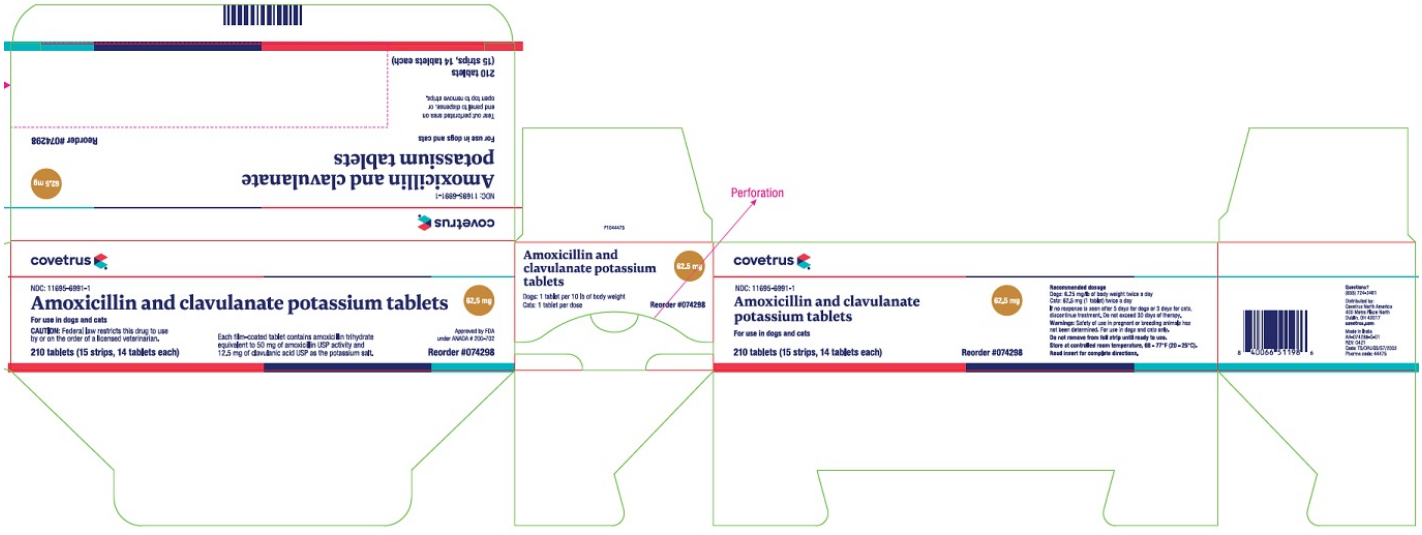

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 11695-6992-1

Amoxicillin and clavulanate potassium tablets

125 mg

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 100 mg of amoxicillin USP activity and 25 mg of clavulanic acid USP as the potassium salt

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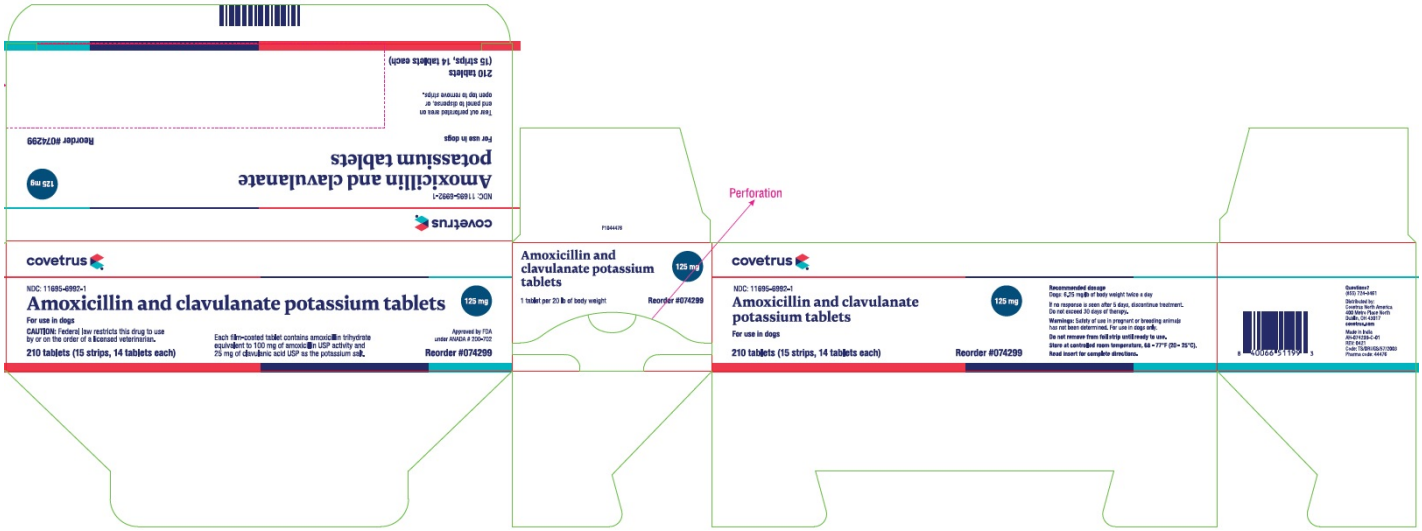
210 tablets (15 strips, 14 tablets each)



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 11695-6993-1

Amoxicillin and clavulanate potassium tablets

250 mg

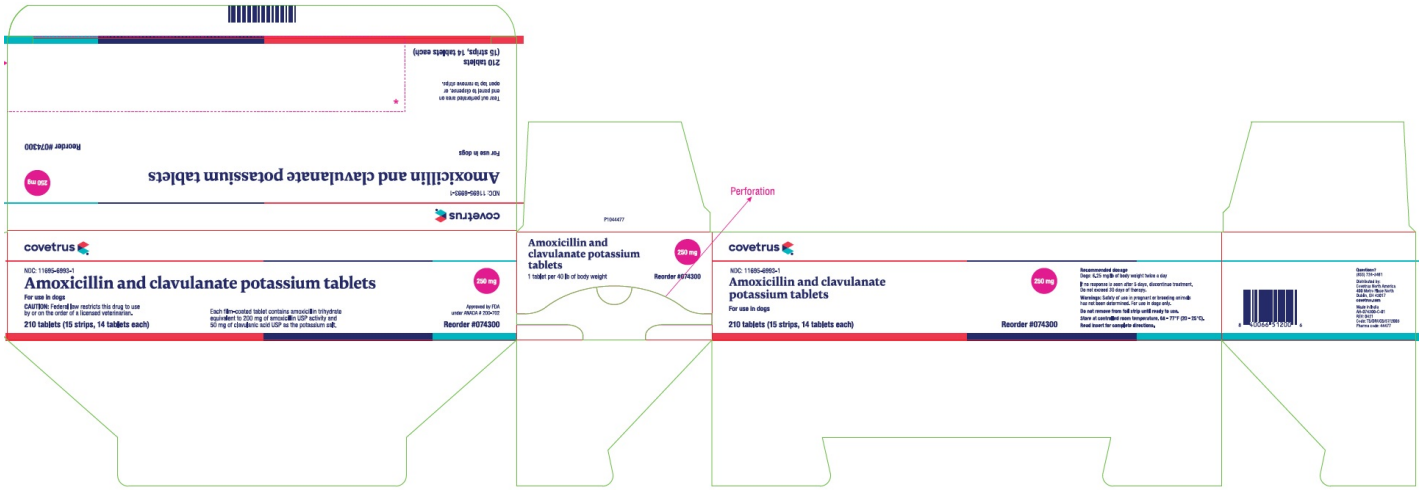
For use in dogs

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

210 tablets (15 strips, 14 tablets each)

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



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 11695-6994-1

Amoxicillin and clavulanate potassium tablets

375 mg

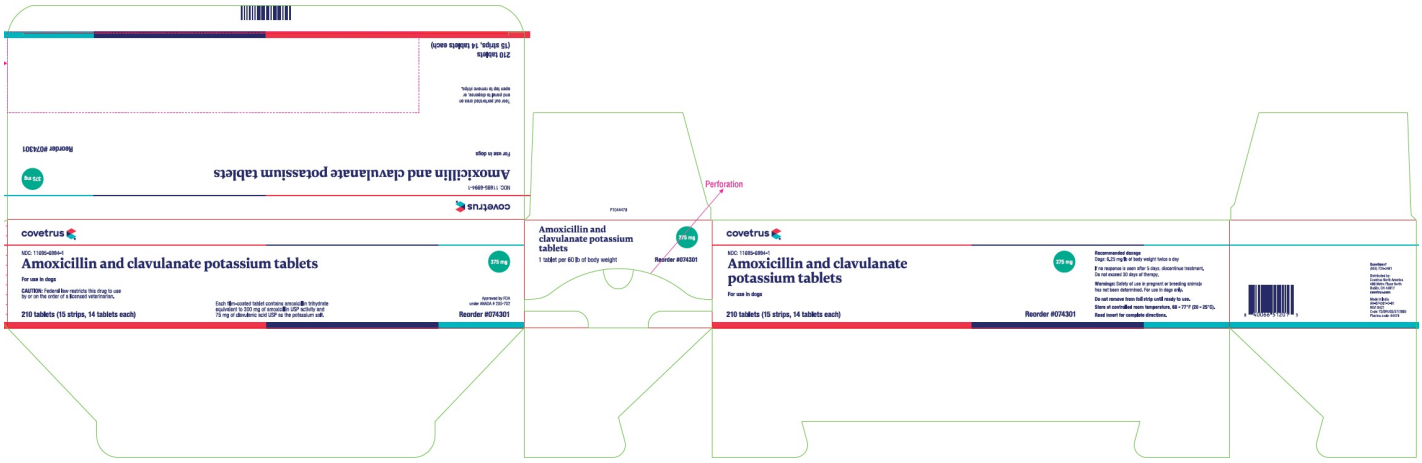
For use in dogs

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

210 tablets (15 strips 14 tablets each)



AMOXICILLIN AND CLAVULANATE POTASSIUM

amoxicillin and clavulanate potassium tablet, coated

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:11695-6991
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMOXICILLIN (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	50 mg
CLAVULANATE POTASSIUM (UNII: Q42OMW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	12.5 mg

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11695-6991-1	15 in 1 CARTON		
1		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200702	07/22/2021	

AMOXICILLIN AND CLAVULANATE POTASSIUM

amoxicillin and clavulanate potassium tablet, coated

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:11695-6992
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMOXICILLIN (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	100 mg
CLAVULANATE POTASSIUM (UNII: Q42OMW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	25 mg

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	9mm

Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-6992-1	15 in 1 CARTON		
1		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200702	07/22/2021	

AMOXICILLIN AND CLAVULANATE POTASSIUM

amoxicillin and clavulanate potassium tablet, coated

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:11695-6993
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMOXICILLIN (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	200 mg
CLAVULANATE POTASSIUM (UNII: Q42OMW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	50 mg

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-6993-1	15 in 1 CARTON		
1		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200702	07/22/2021	

AMOXICILLIN AND CLAVULANATE POTASSIUM

amoxicillin and clavulanate potassium tablet, coated

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:11695-6994
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMOXICILLIN (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	300 mg
CLAVULANATE POTASSIUM (UNII: Q42OMW3AT8) (CLAVULANIC ACID - UNII:23521W1S24)	CLAVULANIC ACID	75 mg

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11695-6994-1	15 in 1 CARTON		
1		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200702	07/22/2021	

Labeler - Covetrus (603750329)

Revised: 8/2021 Covetrus