AMOXI-TABS- amoxicillin tablet, film coated Zoetis Inc.

amoxi**∻**tabs® (amoxicillin tablets), USP

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

Amoxi-Tabs (amoxicillin tablets) is a semisynthetic antibiotic with a broad spectrum of activity. It provides bactericidal activity against a wide range of common gram-positive and gram-negative pathogens. Chemically, it is D(-)-a-amino-p-hydroxybenzyl penicillin trihydrate.

CLINICAL PHARMACOLOGY

Amoxi-Tabs is stable in the presence of gastric acid and may be given without regard to meals. It is rapidly absorbed after oral administration. It diffuses readily into most body tissues and fluids with the exception of brain and spinal fluid, except when meninges are inflamed. Most of the amoxicillin is excreted unchanged in the urine.

Amoxicillin is similar to ampicillin in its bactericidal action against susceptible organisms. It acts through the inhibition of biosynthesis of cell wall mucopeptide. *In vitro* and/or *in vivo* studies have demonstrated the susceptibility of most strains of the following grampositive and gram-negative bacteria: a- and b-haemolytic streptococci, nonpenicillinase-producing staphylococci, *Streptococcus faecalis*, *Escherichia coli*, and *Proteus mirabilis*. Because it does not resist destruction by penicillinase, it is not effective against penicillinase-producing bacteria, particularly resistant staphylococci. All strains of *Pseudomonas* and most strains of *Klebsiella* and *Enterobacter* are resistant

INDICATIONS AND USAGE

Dogs: Amoxi-Tabs are indicated in the treatment of susceptible strains of the organisms causing the following infections:

Respiratory tract infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*.

Genitourinary tract infections (cystitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*.

Gastrointestinal tract infections (bacterial gastroenteritis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*.

Bacterial dermatitis due to *Staphylococcus aureus*, *Streptococcus* spp., and *Proteus mirabilis*.

Soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus* aureus, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*.

Cats: Amoxi-Tabs are indicated in the treatment of susceptible strains of the organisms causing the following infections:

Upper respiratory tract infections due to *Staphylococcus aureus*, *Streptococcus* spp., and *E. coli*.

Genitourinary tract infections (cystitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*.

Gastrointestinal tract infections due to E. coli.

Skin and soft tissue infections (abscesses, lacerations, and wounds) due to Staphylococcus aureus, Streptococcus spp., E. coli, and Pasteurella multocida.

As with all antibiotics, appropriate *in vitro* culturing and susceptibility testing of samples taken before treatment should be conducted.

CONTRAINDICATIONS

The use of this drug is contraindicated in animals with a history of an allergic reaction to penicillin.

WARNING

For use in dogs and cats only

ADVERSE REACTIONS

Amoxicillin is a semisynthetic penicillin and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids

DOSAGE AND ADMINISTRATION

Dogs: The recommended dosage is 5 mg/lb of body weight twice a day.

Cats: The recommended dosage is 50 mg (5–10 mg/lb) once a day.

Dosage should be continued for 5–7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy.

Do Not Store at Temperatures Above 25°C (77°F)

Keep Bottle Tightly Closed.

HOW SUPPLIED

Amoxi-Tabs are supplied in 5 strengths: 50 mg, 100 mg, 150 mg, and 200 mg in bottles of 500 tablets; 400 mg in bottles of 250 tablets.

Approved by FDA under NADA # 055-078 Approved by FDA under NADA # 055-081

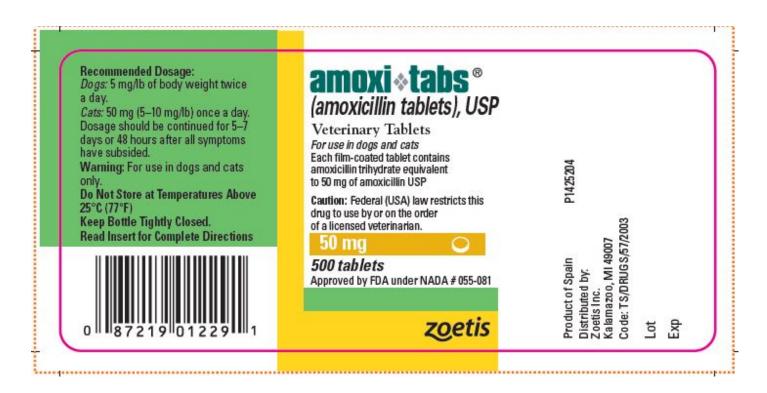
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P1523357

Revised: January 2020

PRINCIPAL DISPLAY PANEL - 50 mg Tablet Bottle Label



PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle Label

Recommended Dosage:

Dogs: 5 mg/lb of body weight twice a day.

Cats: 50 mg (5-10 mg/lb) once a day. Dosage should be continued for 5-7 days or 48 hours after all symptoms have subsided.

Warning: For use in dogs and cats only.

Do Not Store at Temperatures Above 25°C (77°F) Keep Bottle Tightly Closed. **Read Insert for Complete Directions**



amoxi + tabs ° (amoxicillin tablets), USP

Veterinary Tablets

For use in dogs and cats

Each film-coated tablet contains amoxicillin trihydrate equivalent to 100 mg of amoxicillin USP

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

100 mg

500 tablets

Approved by FDA under NADA # 055-081

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AMOXI-TABS

amoxicillin tablet, film coated

Product Information

Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:54771-6042 **Route of Administration ORAL**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
(2S,5R,6R)-6-((R)-(-)-2-AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO)-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCL(3.2.0)HEPTANE-2-CARBOXYLIC ACID TRIHYDRATE (UNII:	AMOXICILLIN	50 mg

804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)

Product Characteristics			
Color	yellow	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	BMP193
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-6042-2	500 in 1 BOTTLE		

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NADA055081	06/02/1978			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

AMOXI-TABS

amoxicillin tablet, film coated

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-6043
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
(2S,5R,6R)-6-((R)-(-)-2-AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO)-OXO-4-THIA-1-AZABICYCL(3.2.0)HEPTANE-2-CARBOXYLIC ACID TRI 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)		100 mg	

Product Characteristics				
Color	blue	Score	no score	
Shape	ROUND	Size	9mm	
Flavor		Imprint Code	BMP202	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-6043-3	500 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA055081	06/02/1978	

Revised: 6/2021 Zoetis Inc.