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

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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  $D(-)-\alpha$ -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 gram-positive and gram-negative bacteria: a- and b-haemolytic streptococci, nonpenicillinaseproducing 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*.

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*.

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

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**

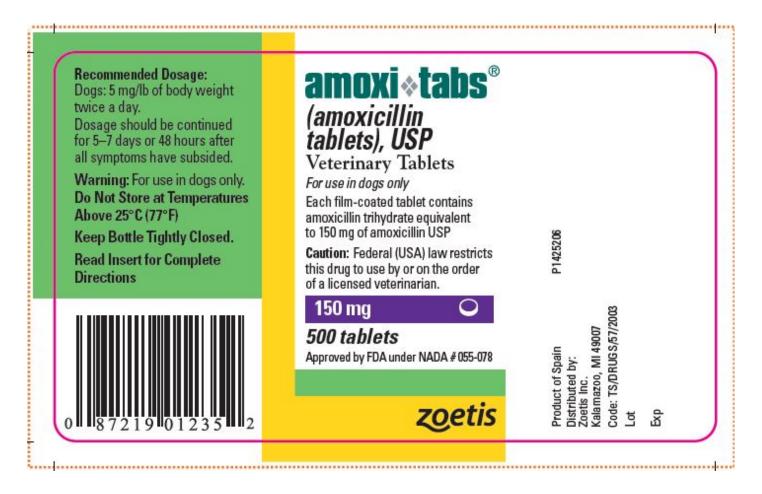
Amoxi-Tabs are supplied in 5 strengths: 50 mg, 100 mg, 150 mg, and 200 mg in bottles of 500 tablets; 400 mg in bottles of 250 tablets.

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

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Distributed by: Zoetis Inc. Kalamazoo, MI 49007

### PRINCIPAL DISPLAY PANEL - 150 mg Tablet Bottle Label



PRINCIPAL DISPLAY PANEL - 200 mg Tablet Bottle Label



PRINCIPAL DISPLAY PANEL - 400 mg Tablet Bottle Label

### Recommended Dosage:

Dogs: 5 mg/lb of body weight twice a day. Dosage should be continued for 5–7 days or 48 hours after all symptoms have subsided.



Warning: Not for use in animals which are raised for food production.

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 only

Each film-coated tablet contains amoxicillin trihydrate equivalent to 400 mg of amoxicillin USP

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

400 mg



## 250 tablets

Approved by FDA under NADA # 055-078

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ted by: nc. zoo, MI 49007

Product of Spain

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### **AMOXI-TABS**

amoxicillin tablet, film coated

### **Product Information**

Product TypePRESCRIPTION ANIMAL DRUGItem Code (Source)NDC:54771-8007Route of AdministrationORAL

### **Active Ingredient/Active Moiety**

Ingredient Name
Basis of Strength
AMO XICILLIN (UNII: 804826J2HU) (AMO XICILLIN ANHYDROUS - UNII:9EM05410Q9)
AMO XICILLIN ANHYDROUS
150 mg

#### **Product Characteristics**

ColorPURPLEScoreno scoreShapeROUNDSize10 mm

Flavor	Imprint Code	BMP208
Contains		

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:54771-8007-7	500 in 1 BOTTLE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA055078	02/04/1976		

### **AMOXI-TABS**

amoxicillin tablet, film coated

<b>Product Information</b>			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-6044
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AMO XICILLIN (UNII: 804826J2HU) (AMO XICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	200 mg

Product Characteristics				
Color	ORANGE (Coral)	Score	no score	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	BMP203	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:54771-6044-4	500 in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA055078	02/04/1976		

## **AMOXI-TABS**

amoxicillin tablet, film coated

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Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-6046
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Route of Administration ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMO XICILLIN (UNII: 804826J2HU) (AMO XICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	400 mg

Product Characteristics			
Color	GREEN	Score	no score
Shape	ROUND	Size	14mm
Flavor		Imprint Code	BMP196
Contains			

Packaging									
#	Item Code	Package Description	Marketing Start Date	Marketing End Date					
1	NDC:54771-6046-6	250 in 1 BOTTLE							

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
NADA	NADA055078	02/04/1976						

## **Labeler -** Zoetis Inc. (828851555)

Establishment								
Name	Address	ID/FEI	Business Operations					
Aurobindo Pharma Limited		918917683	MANUFACTURE					

Revised: 5/2020 Zoetis Inc.