AMOXI-DROP- amoxicillin suspension
Zoetis Inc.

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amoxi-drop®
(amoxicillin)

Amoxi-Drop

(amoxicillin for oral suspension), USP

For veterinary oral suspension

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-Drop (amoxicillin for oral suspension), USP 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(-)-α-amino-p-hydroxybenzyl penicillin trihydrate.

CLINICAL PHARMACOLOGY

Amoxi-Drop 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: α- and β-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

Dogs

Amoxi-Drop is 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-Drop is indicated in the treatment of susceptible strains of the organisms causing the following infections:

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

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

Gastrointestinal tract infections due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.

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

CONTRAINDICATIONS

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

WARNINGS

For use in dogs and cats only. Not for use in animals which are raised for food production.

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. Administer twice daily for 5–7 days. Continue for 48 hours after all symptoms have subsided.

Cats

The recommended dosage is 50 mg (5–10 mg/lb). Administer once daily for 5–7 days. Continue for 48 hours after all symptoms have subsided.

Directions for Mixing Oral Suspension:

Add required amount of water (see following table) to the bottle and shake vigorously. Each mL of suspension will contain 50 mg of amoxicillin as the trihydrate.

Bottle Size	Amount of Water Required for Reconstitution
15 mL	12 mL
30 mL	23 mL

Note: Any unused portion of the reconstituted suspension must be discarded after 14 days. After mixing, refrigeration preferable, but not required.

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

HOW SUPPLIED

Amoxi-Drop is supplied in 15-mL bottles containing 0.75 g and 30-mL bottles containing 1.5 g of amoxicillin activity. When reconstituted with required amount of water, each mL contains 50 mg of amoxicillin as the trihydrate.

Approved by FDA under NADA # 055-085

PRODUCT OF SPAIN

zoetis

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

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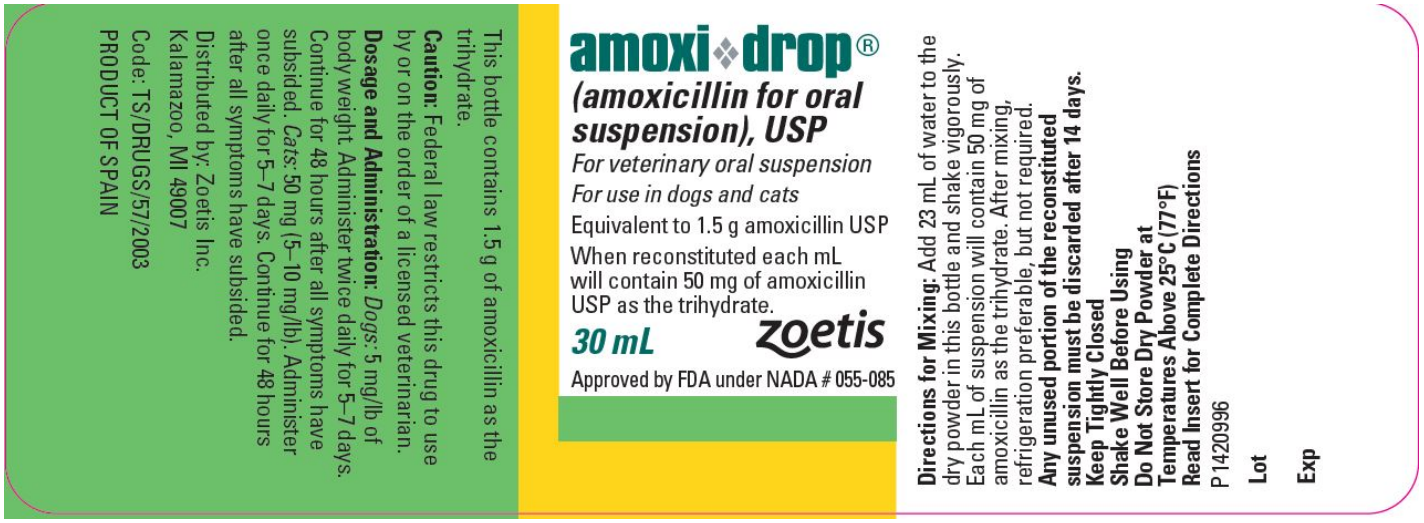
P1518394

PRINCIPAL DISPLAY PANEL - 15 mL Label

PRINCIPAL DISPLAY PANEL - 30 mL Label



AMOXI-DROP

amoxicillin suspension

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:54771-6036
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 in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54771-6036-1	30 mL in 1 BOTTLE, DROPPER		
2	NDC:54771-6036-6	15 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA055085	01/28/1977	

Labeler - Zoetis Inc. (828851555)

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