AMOXI-TABS- amoxicillin tablet, film coated Pfizer Animal Health

amoxiltabs® (amoxicillin)

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) 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: 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 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)

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.

NADA #55-078 & #55-081, Approved by FDA

MADE IN INDIA

Distributed by:

Pfizer Animal Health

Div. of Pfizer Inc

NY, NY 10017

P1501359 75-8004-06IN.00 Jan 2008

PRINCIPAL DISPLAY PANEL - 150 mg Tablet Bottle Label

amoxiltabs[®] (amoxicillin) Veterinary Tablets

For use in dogs only

Each film-coated tablet contains amoxicillin trihydrate equivalent to 150 mg of amoxicillin.

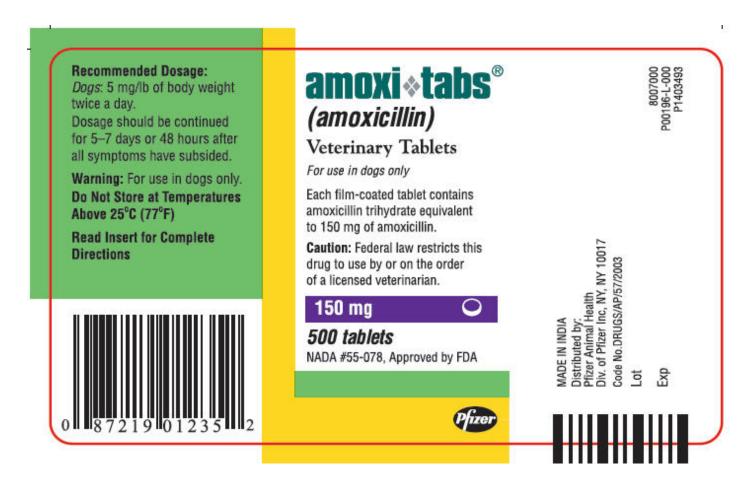
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

150 mg

500 tablets

NADA #55-078, Approved by FDA

Pfizer



PRINCIPAL DISPLAY PANEL - 200 mg Tablet Bottle Label amoxiltabs®

(amoxicillin) Veterinary Tablets

For use in dogs only

Each film-coated tablet contains amoxicillin trihydrate equivalent to 200 mg of amoxicillin.

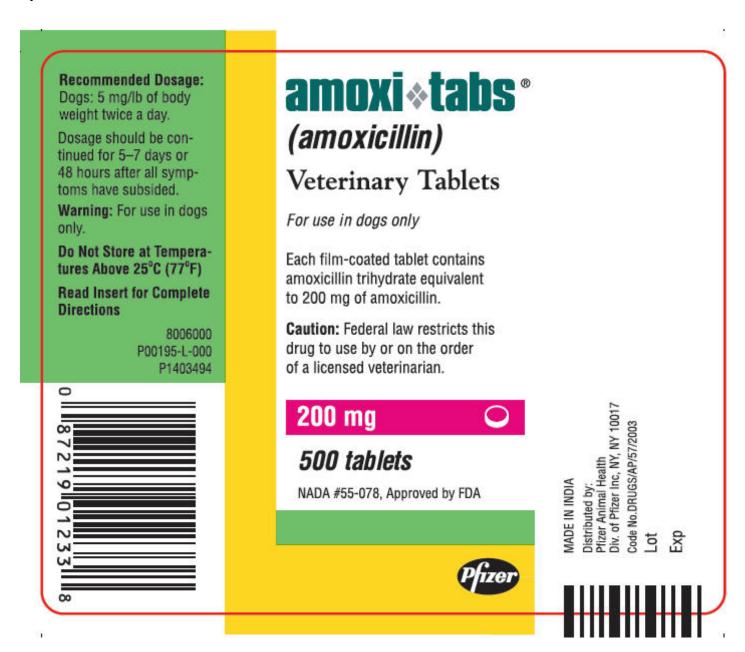
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

200 mg

500 tablets

NADA #55-078, Approved by FDA

Pfizer



amoxi∃tabs[®] *(amoxicillin)* Veterinary Tablets

For use in dogs only

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

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

400 mg

250 tablets

NADA #55-078, Approved by FDA

Pfizer

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) Read Insert for Complete Directions

> 8008000 P00197-L-000 P1403493



amoxi*tabs®

(amoxicillin)

Veterinary Tablets

For use in dogs only

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

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

400 mg



250 tablets

NADA #55-078, Approved by FDA

MADE IN INDIA Distributed by: Pfizer Animal Health

Div. of Pfizer Inc, NY, NY 10017 Code No.DRUGS/AP/57/2003

Lot Exn





AMOXI-TABS

amoxicillin tablet, film coated

| Product Information | | | |
|-------------------------|-----------------------------------|--------------------|--------------------|
| Product Type | PRESCRIPTION ANIMAL DRUG LABEL | Item Code (Source) | NDC:61106- 8007 |
| Route of Administration | ORAL | DEA Schedule | |

| Active Ingredient/Active Moiety | | | |
|-------------------------------------|-------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| amoxicillin (amoxicillin anhydrous) | amo xicillin anhydro us | 150 mg | |

| Product Characteristics | | | | |
|-------------------------|--------|--------------|----------|--|
| Color | PURPLE | Score | no score | |
| Shape | ROUND | Size | 10 mm | |
| Flavor | | Imprint Code | BMP208 | |
| Contains | | | | |

| P | Packaging | | | | |
|---|------------------|---------------------|----------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:61106-8007-7 | 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

| Product Information | | | | |
|-------------------------|-----------------------------------|--------------------|--------------------|--|
| Product Type | PRESCRIPTION ANIMAL DRUG LABEL | Item Code (Source) | NDC:61106- 6044 | |
| Route of Administration | ORAL | DEA Schedule | | |

| Active Ingredient/Active Moiety | | | |
|-------------------------------------|-----------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| amoxicillin (amoxicillin anhydrous) | amoxicillin anhydrous | 200 mg | |
| | | | |
| | | | |

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

| Packaging | g | | | |
|------------|----------|---------------------|----------------------|---------------------------|
| # Ite: | m Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:6110 | 6-6044-4 | 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

| Product Information | | | | |
|-------------------------|-----------------------------------|--------------------|--------------------|--|
| Product Type | PRESCRIPTION ANIMAL DRUG LABEL | Item Code (Source) | NDC:61106- 6046 | |
| Route of Administration | ORAL | DEA Schedule | | |

| Active Ingredient/Active Moiety | | | |
|-------------------------------------|-----------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| amoxicillin (amoxicillin anhydrous) | 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:61106-6046-6 | 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 - Pfizer Animal Health (039055157)

Registrant - Pfizer Inc (943955690)

| Establishment | | | | |
|-----------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Aurobindo Pharma Ltd. | | 918917683 | MANUFACTURE | |

| Establishment | | | | |
|-------------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Beecham Pharmaceuticals | | 595132580 | API MANUFACTURE | |

Revised: 11/2012 Pfizer Animal Health