

AMPICILLIN SODIUM- ampicillin sodium injection, powder, for solution
US Vet Inc

Ampicillin Sodium
For Intravenous or Intramuscular Use in Horses Only

DESCRIPTION

Ampicillin sodium is a semisynthetic penicillin with a broad spectrum of activity. Ampicillin is derived from the penicillin nucleus, 6-aminopenicillanic acid (6 APA). Chemically it is D(-) α -aminobenzyl penicillin sodium salt.

ACTION

Ampicillin sodium provides bactericidal activity against a wide range of common Gram-positive and Gram-negative pathogens. Ampicillin's activity occurs during the stage of active multiplication of the pathogen and acts through inhibition of biosynthesis of cell wall mucopeptide. *In vivo* studies have demonstrated the susceptibility of many strains of the following Gram-positive bacteria: *Staphylococcus* spp. and *Streptococcus* spp. (including *S. equi*). *In vivo* studies have also demonstrated the susceptibility of many strains of the following Gram-negative bacteria: *E. coli* and *Proteus mirabilis*. Because it does not resist destruction by penicillinase, it is not effective against penicillinase-producing bacteria, particularly resistant staphylococci. Most strains of *Pseudomonas*, *Klebsiella* and *Aerobacter* are resistant.

Ampicillin sodium diffuses readily into all body tissues and fluids, with the exception of brain and spinal fluid except when the meninges are inflamed. It produces high and persistent blood levels. Most of the ampicillin is excreted unchanged in the urine.

INDICATIONS

Ampicillin sodium is indicated in the treatment of susceptible strains of the organisms causing the following infections in the horse: Respiratory tract infections (pneumonia and strangles) due to *Staphylococcus* spp., *Streptococcus* spp. (including *S. equi*), *E. coli*, and *Proteus mirabilis*.

Skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*.

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.

ADVERSE REACTIONS

Ampicillin is a semisynthetic penicillin and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids. Possible minor irritation at the injection site may occur.

WARNINGS

Restricted Drug (California) - Use only as Directed.

Do not use in horses intended for human consumption.

Not for human use.

CAUTION

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

DOSAGE AND ADMINISTRATION

HORSES - The recommended dose is 3 mg per pound of body weight administered twice a day. Ampicillin sodium may be administered by either the intravenous or intramuscular route. Treatment should be continued 48 hours after all symptoms have subsided. If no response is seen in 4-5 days, diagnosis should be re-evaluated.

DIRECTIONS FOR USE

The dry filled vials should be reconstituted immediately before use by the addition of the appropriate amount of Sterile Water for Injection, USP indicated below. This results in a final concentration of approximately 300 mg per mL.

<u>Vial Size</u>	<u>Amount of Diluent to be Added</u>
1 Gram	2.6 mL
3 Gram	7.6 mL

Stability studies with the concentrated product (300 mg/mL) demonstrated that ampicillin is stable for 1 hour at room temperature (70° - 75° F).

HOW SUPPLIED

Ampicillin Sodium is supplied in vials containing 1 gram and 3 grams of ampicillin activity.

Store dry powder at room temperature, 15° to 30°C (59° to 86°F).

NDC 86108-335-01 1 gm vial

NDC 86108-335-03 3 gm vial

Approved by FDA under ANADA # 200-335

Manufactured for:

US VET Inc.

Hamilton, NY 13346

INS15793 04 Rev. 05/2020

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 86108-335-01

AMPICILLIN SODIUM

For Intravenous or Intramuscular Use
in Horses Only

1 gram

Each vial contains: Ampicillin sodium equivalent to 1 gram ampicillin.

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VET
VETERINARY PRODUCTS

Mfd for: US VET Inc.
Hamilton, NY 13346

Recommended Dose:
3 mg per pound of body weight twice daily.

RECONSTITUTION INSTRUCTIONS:
Dry filled vials should be reconstituted immediately before use by the addition of 2.6 mL of Sterile Water for Injection, USP which results in a final concentration of 300 mg per mL.

WARNING: Do NOT use in horses intended for human consumption.

READ ACCOMPANYING INSERT BEFORE USE

Store dry powder at room temperature, 15° to 30° C (59° to 86° F).

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LBL15764-04 Rev. 05/2020

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LOT EXP

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Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86108-335
Route of Administration	INTRAVENOUS, INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPICILLIN SODIUM (UNII: JFN36L5S8K) (AMPICILLIN - UNII:7C782967RD)	AMPICILLIN	1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86108-335-01	10 in 1 TRAY		
1		1 in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200335	11/02/2020	

Labeler - US Vet Inc (117160633)

Establishment

Name	Address	ID/FEI	Business Operations
GC Hanford Manufacturing Company		002238863	MANUFACTURE, ANALYSIS

Revised: 11/2020

US Vet Inc