AMPICILLIN SODIUM- ampicillin sodium injection, powder, for solution
GC Hanford Manufacturing Company

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 vitroculturing 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.

Vial Size	Amount of Diluent to be Added
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 10515-335-01 1 gm vial
NDC 10515-335-03 3 gm vial

ANADA 200-335 Approved by FDA

Manufactured by:
G.C. Hanford Mfg. Co.

Syracuse, NY 13201 INS15793 03 7/2011

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 10515-335-01

AMPICILLIN SODIUM

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1 GRAM

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

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Mfd. By G.C. Hanford Mfg. Co.
Syracuse, NY 13201

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ampicillin sodium injection, powder, for solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:10515-335
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:10515-335-01	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	01/30/2009	

Labeler - GC Hanford Manufacturing Company (002238863)

Establishment

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

Revised: 10/2017 GC Hanford Manufacturing Company