NADA 55-030, Approved by FDA

Polyflex®

Ampicillin for Injectable Suspension, Veterinary

Boehringer Ingelheim

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

Description: Polyflex (ampicillin for injectable suspension, veterinary) is a broad-spectrum penicillin which has bactericidal activity against a wide range of common gram-positive and gram-negative bacteria.

Each 25 g vial contains: 25 g ampicillin activity as ampicillin trihydrate, 90 mg methylparaben (as preservative), 10 mg propylparaben (as preservative), 200 mg lecithin, 500 mg povidone, 200 mg sodium chloride, 600 mg sodium citrate anhydrous.

Each 10 g vial contains: 10 g ampicillin activity as ampicillin trihydrate, 36 mg methylparaben (as preservative), 4 mg propylparaben (as preservative), 80 mg lecithin, 200 mg povidone, 80 mg sodium chloride, 240 mg sodium citrate anhydrous.

Indications: Polyflex has proved effective in the treatment of many infections previously beyond the spectrum of penicillin therapy. This drug is particularly indicated in the treatment of the following infections caused by susceptible strains of organisms:

Dogs and Cats – Respiratory Tract Infections: Upper respiratory infections, tonsillitis and bronchopneumonia due to hemolytic streptococci, *Staphylococcus aureus, Escherichia coli, Proteus mirabilis* and *Pasteurella* spp.

Urinary Tract Infections due to *Proteus mirabilis, Escherichia coli, Staphylococcus* spp., hemolytic streptococci and *Enterococcus* spp.

Gastrointestinal Infections due to *Enterococcus* spp., *Staphylococcus* spp. and *Escherichia coli.*

Skin, Soft Tissue and Post-Surgical Infections: Abscesses, pustular dermatitis, cellulitis and infections of the anal gland, due to *Escherichia coli, Proteus mirabilis,* hemolytic streptococci, *Staphylococcus* spp. and *Pasteurella* spp.

Cattle and Calves Including Non-Ruminating (Veal Calves) – Respiratory Tract Infections: Bacterial pneumonia (shipping fever, calf pneumonia and bovine pneumonia) caused by *Aerobacter* spp., *Klebsiella* spp., *Staphylococcus* spp., *Streptococcus* spp., *Pasteurella multocida* and *E. coli* susceptible to ampicillin trihydrate.

Dosage: The dosage of Polyflex will vary according to the animal being treated, the severity of the infection and the animal's response.

Dogs and Cats – The recommended dose for dogs or cats is 3 mg/lb of body weight administered twice daily by subcutaneous or intramuscular injection.

Cattle and Calves Including Non-Ruminating (Veal Calves) – From 2 mg to 5 mg/lb of body weight once daily by intramuscular injection. Do not treat for more than 7 days.

In all species, 3 days treatment is usually adequate, but treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic.

Directions for Use: The multi-dose dry-filled vials should be reconstituted to the desired concentration by adding the required amount of Sterile Water for Injection, USP, according to label directions. **SHAKE WELL.**

After reconstitution this product is stable for 3 months under refrigeration and will be white to pale yellow in color.

At the time of reconstitution the vial should be dated and the concentration noted on the label.

Contraindications: A history of allergic reactions to penicillin, cephalosporins or their analogues should be considered a contraindication for the use of this agent.

Residue Warnings: Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment, and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment, and for 144 hours (6 days) after the last treatment.

Precautions: Because it is a derivative of 6-aminopenicillanic acid, Polyflex has the potential for producing allergic reactions. If they should occur, Polyflex should be discontinued and the subject treated with the usual agents (antihistamines, pressor amines, corticosteroids).

Clinical Pharmacology: The antimicrobial action of ampicillin is bactericidal, and only a small percentage of the antibiotic is serum-bound. Peak serum levels in dogs and cats are reached approximately one-half hour following subcutaneous or intramuscular injection, and in cattle 1 hour to 2 hours following intramuscular injection.

In vitro studies have demonstrated sensitivity of the following organisms to ampicillin: gram-positive bacteria – alpha- and beta-hemolytic streptococci, staphylococci (non-penicillinase-producing), *Bacillus anthracis* and most strains of enterococci and clostridia; gram-negative bacteria – *Proteus mirabilis, E. coli* and many strains of Salmonella and *Pasteurella multocida.*

The drug does not resist destruction by penicillinase and, hence, is not effective against strains of staphylococci resistant to penicillin G. Susceptibility tests should be conducted to estimate the *in vitro* susceptibility of bacterial isolates to ampicillin.

Storage: Store at controlled room temperature 15 - 30°C (59 -86°F). After reconstitution, store under refrigeration.

How Supplied: Polyflex (ampicillin for injectable suspension, veterinary) is supplied in vials containing 10 g and 25 g ampicillin activity as ampicillin trihydrate.

NDC 0010-4712-01 – 10 g per vial
NDC 0010-4712-02 – 25 g per vial

Polyflex is a registered trademark of Boehringer Ingelheim Vetmedica, Inc.

Manufactured for:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.
11950 Rev. July 2010 D4470B

NDC 0010-4712-01

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Ampicillin for Injectable Suspension, Veterinary

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

Equivalent to 10 g Ampicillin

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Each vial contains: 10 g ampicillin activity as ampicillin trihydrate, 36 mg methylparaben (as preservative), 4 mg propylparaben (as preservative), 80 mg lecithin, 200 mg povidone, 80 mg sodium chloride, 240 mg sodium citrate anhydrous.

After reconstitution, this product is stable for 3 months under refrigeration. **SHAKE WELL.**

Sterile water for injection to add per vial:	Ampicillin activity per mL:
30.5 mL	250 mg

Date Reconstituted_____ / _____mg/mL

Dosage: Refer to package insert for full dosage information and directions for use.

Residue Warnings: Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment, and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment, and for 144 hours (6 days) after the last treatment.

Store at controlled room temperature 15 - 30°C (59 - 86°F). After reconstitution, store under refrigeration.

Manufactured for:
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St. Joseph, MO 64506 U.S.A.

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Boehringer Ingelheim

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NDC 0010-4712-02

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Ampicillin for Injectable Suspension, Veterinary

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

Equivalent to 25 g Ampicillin

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Each vial contains: 25 g ampicillin activity as ampicillin trihydrate, 90 mg methylparaben (as preservative), 10 mg propylparaben (as preservative), 200 mg lecithin, 500 mg povidone, 200 mg sodium chloride, 600 mg sodium citrate anhydrous.

After reconstitution, this product is stable for 3 months under refrigeration. **SHAKE WELL.**

Sterile water for injection to add per vial:	Ampicillin activity per mL:
104.5 mL	200 mg
79.0 mL	250 mg
41.0 mL	400 mg

Date Reconstituted _____ / _____ mg/mL

Dosage: Dogs and Cats - 3 mg/lb of body weight twice daily by subcutaneous or intramuscular injection.

Cattle and Calves Including Non-Ruminating (Veal Calves) – From 2 mg to 5 mg/lb of body weight once daily by intramuscular injection. Do not treat for more than 7 days. See package insert for additional dosage recommendations.

Residue Warnings: Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment, and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment, and for 144 hours (6 days) after the last treatment.

Store at controlled room temperature 15 - 30°C (59 - 86°F). After reconstitution, store under refrigeration.

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