POLYFLEX- ampicillin injection, powder, for suspension
Boehringer Ingelheim Animal Health USA Inc.

Polyflex®
(ampicillin for injectable suspension)

For veterinary use only

CAUTION:

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

DESCRIPTION:

POLYFLEX (ampicillin for injectable suspension) 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.

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.**

The appearance 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 or below 25°C (77°F) with excursions permitted up to 30°C (86°F). After reconstitution, store under refrigeration. Use within 3 months of first puncture. Avoid freezing.

HOW SUPPLIED:

POLYFLEX (ampicillin for injectable suspension) is supplied in vials containing 25 g ampicillin activity as ampicillin trihydrate.

NDC 0010-4712-02 — 25 g per vial

POLYFLEX® is a registered trademark of Boehringer Ingelheim Animal Health USA Inc.

Approved by FDA under NADA # 055-030

Marketed by:

Boehringer Ingelheim Animal Health USA Inc.

Duluth, GA 30096

Made in Italy

Rev. 9/2020
471209-01

Principal Display Panel – 25 g Vial Label

NDC 0010-4712-02

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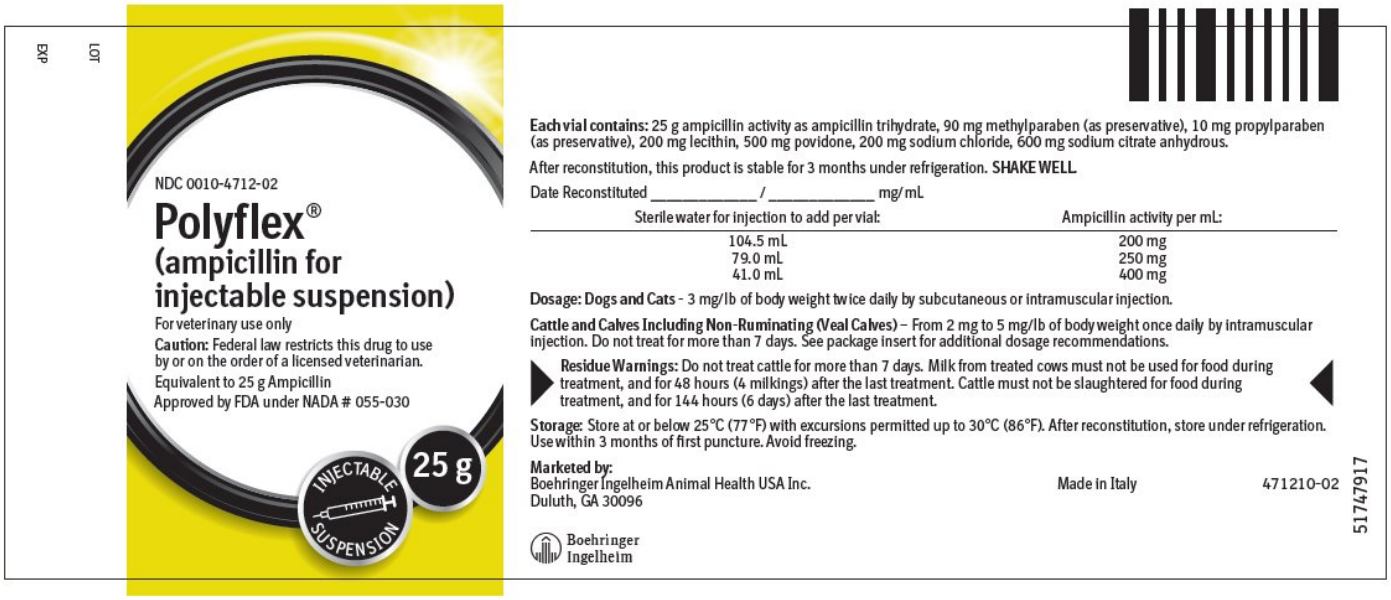
Equivalent to 25 g Ampicillin

Approved by FDA under NADA # 055-030



Principal Display Panel - 25 g Display Carton

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POLYFLEX

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Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:0010-4712
Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMPICILLIN TRIHYDRATE (UNII: HXQ6A1N7R6) (AMPICILLIN - UNII:7C782967RD)	AMPICILLIN	250 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	0.9 mg in 1 mL
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.1 mg in 1 mL
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	2 mg in 1 mL
POVIDONE K30 (UNII: U725QWY32X)	5 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	2 mg in 1 mL
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	6 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4712-02	79 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA055030	10/29/1971	

Labeler - Boehringer Ingelheim Animal Health USA Inc. (007134091)

Revised: 5/2022 Boehringer Ingelheim Animal Health USA Inc.