Penicillin V Potassium Tablets, USP

Penicillin V Potassium Tablets, USP
250 mg (400,000 Units)
500 mg (800,000 Units)

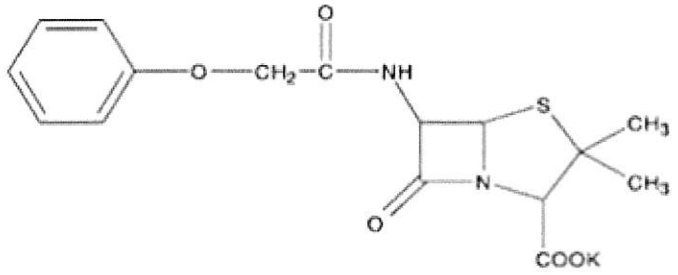
Rx Only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of penicillin V potassium tablets and other antibacterial drugs, penicillin V potassium tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION

Penicillin V is the phenoxymethyl analog of penicillin G.

Penicillin V potassium is the potassium salt of penicillin V.



Molecular Formula: $C_{16}H_{17}O_5KN_2S$ Molecular Weight: 388.5

Penicillin V Potassium Tablets, USP for oral administration contain penicillin V potassium equivalent to 250 mg (400,000 units) or 500 mg (800,000 units) penicillin V. In addition, each tablet contains the following inactive ingredients: hydroxypropyl methylcellulose, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide and microcrystalline cellulose.

CLINICAL PHARMACOLOGY

Penicillin V exerts a bactericidal action against penicillin-sensitive microorganisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell-wall mucopeptide. It is not active against the penicillinase-producing bacteria, which include many strains of staphylococci. The drug exerts high *in vitro* activity against staphylococci (except penicillinase-producing strains), streptococci (groups A, C, G, H, L and M), and pneumococci. Other organisms sensitive *in vitro* to penicillin V are *Corynebacterium diphtheriae, Bacillus anthracis, Clostridia, Actinomyces bovis, Streptobacillus moniliformis, Listeria monocytogenes, Leptospira*, and *Neisseria gonorrhoeae. Treponema pallidum* is extremely sensitive.

The potassium salt of penicillin V has the distinct advantage over penicillin G in resistance to inactivation by gastric acid. It may be given with meals; however, blood levels are slightly higher when the drug is given on an empty stomach. Average blood levels are two to five times higher than the levels following the same dose of oral penicillin G and also show much less individual variation.

Once absorbed, penicillin V is about 80% bound to serum protein. Tissue levels are highest in the kidneys, with lesser amounts in the liver, skin, and intestines. Small amounts are found in all other body tissues and the cerebrospinal fluid. The drug is excreted as rapidly as it is absorbed in individuals with normal kidney function; however, recovery of the drug from the urine indicates that only about 25% of the dose given is absorbed. In neonates, young infants, and individuals with impaired kidney function, excretion is considerably delayed.

Table 2. ACCEPTABLE QUALITY CONTROL RANGES

Microorganism	Acceptable Quality Control Ranges	
	Disk diffusion (Zone diameter ranges in mm)	Minimal Inhibitory Concentration Range (MIC in mcg/mL)
Staphylococcus aureus ATCC® 25923	26-37	
Staphylococcus aureus ATCC® 29213		0.25-2
Streptococcus pneumoniae ATCC® 49619	24-30	0.25-1

INDICATIONS AND USAGE

Penicillin V Potassium Tablets, USP are indicated in the treatment of mild to moderately severe infections due to penicillin G-sensitive microorganisms. Therapy should be guided by bacteriological studies (including sensitivity tests) and by clinical response.

NOTE: Severe pneumonia, empyema, bacteremia, pericarditis, meningitis, and arthritis should not be treated with penicillin V during the acute stage. Indicated surgical procedures should be performed.

The following infections will usually respond to adequate dosage of penicillin V.

Streptococcal Infections (without bacteremia)

Mild-to-moderate infections of the upper respiratory tract, scarlet fever, and mild erysipelas.

NOTE: Streptococci in groups A, C, G, H, L, and M are very sensitive to penicillin.

Other groups, including group D (enterococcus), are resistant.

Pneumococcal Infections

Mild to moderately severe infections of the respiratory tract.

Staphylococcal infections – penicillin G-sensitive

Mild infections of the skin and soft tissues.

NOTE: Reports indicate an increasing number of strains of staphylococci resistant to penicillin G, emphasizing the need for culture and sensitivity studies in treating suspected staphylococcal infections.

Fusospirochetosis (Vincent's gingivitis and pharyngitis)

Mild to moderately severe infections of the oropharynx usually respond to therapy with oral penicillin.

NOTE: Necessary dental care should be accomplished in infections involving the gum tissue.

Medical conditions in which oral penicillin therapy is indicated as prophylaxis:

For the prevention of recurrence following rheumatic fever and/or chorea: Prophylaxis with oral penicillin on a continuing basis has proven effective in preventing recurrence of these conditions.

Although no controlled clinical efficacy studies have been conducted, penicillin V has been suggested by the American Heart Association and the American Dental Association for use as an oral regimen for prophylaxis against bacterial endocarditis in patients who have congenital heart disease or rheumatic or other acquired valvular heart disease when they undergo dental procedures and surgical procedures of the upper respiratory tract1. Oral penicillin should not be used in those patients at particularly high risk for endocarditis (e.g., those with prosthetic heart valves or surgically constructed systemic pulmonary shunts).

General

Prescribing penicillin V potassium tablets in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

The oral route of administration should not be relied upon in patients with severe illness, or with nausea, vomiting, gastric dilatation, cardiospasm, or intestinal hypermotility.

Occasional patients will not absorb therapeutic amounts of orally administered penicillin.

In streptococcal infections, therapy must be sufficient to eliminate the organism (10-day minimum); otherwise the sequelae of streptococcal disease may occur. Cultures should be taken following completion of treatment to determine whether streptococci have been eradicated.

Prolonged use of antibiotics may promote the overgrowth of nonsusceptible organisms, including fungi. Should superinfection occur, appropriate measures should be taken.

Information for Patients

Patients should be counseled that antibacterial drugs including penicillin V potassium tablets should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When penicillin V potassium tablets are prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may: (1) decrease the effectiveness of the immediate treatment, and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by penicillin V potassium tablets or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

ADVERSE REACTIONS

Although the incidence of reactions to oral penicillins has been reported with much less frequency than following parenteral therapy, it should be remembered that all degrees of hypersensitivity, including fatal anaphylaxis, have been reported with oral penicillin.

The most common reactions to oral penicillin are nausea, vomiting, epigastric distress, diarrhea, and black hairy tongue. The hypersensitivity reactions reported are skin eruptions (maculopapular to exfoliative dermatitis), urticaria and other serum-sicknesslike reactions, laryngeal edema, and anaphylaxis.

Fever and eosinophilia may frequently be the only reaction observed. Hemolytic anemia, leukopenia, thrombocytopenia, neuropathy, and nephropathy are infrequent reactions and usually associated with high doses of parenteral penicillin.

To report SUSPECTED ADVERSE REACTIONS, contact West-Ward Pharmaceutical Corp. at 1-877-233-2001, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

The dosage of penicillin V potassium tablets should be determined according to the sensitivity of the causative microorganisms and the severity of infection, and adjusted to the clinical response of the patient.

The usual dosage recommendations for adults and children 12 years and over are as follows:

Streptococcal Infections

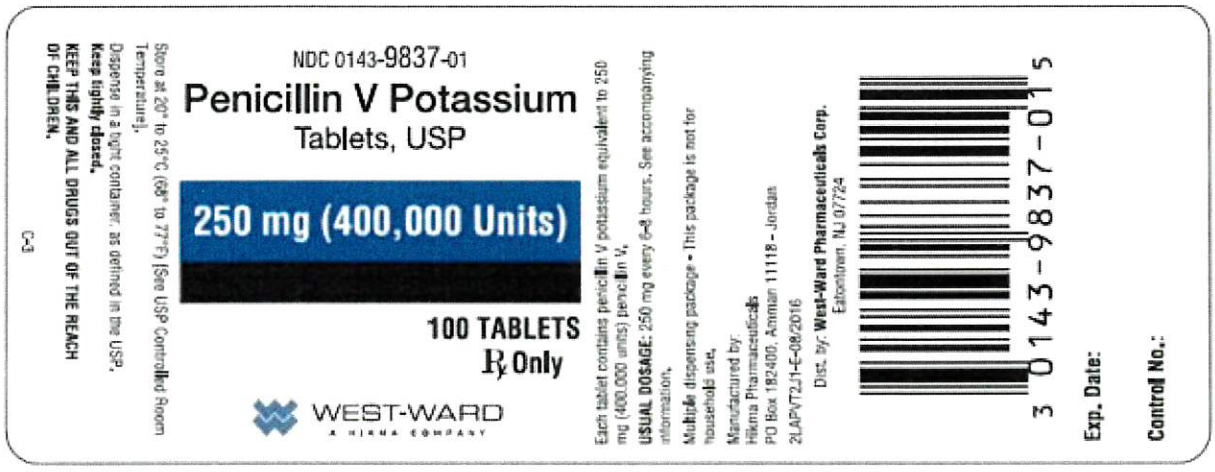
Distributed by:
West-Ward Pharmaceuticals Corp.
Eatontown, NJ 07724 USA

Manufactured by:
HIKMA Pharmaceuticals
P.O. Box 182400
Amman 11118 - Jordan

Issued October 2016

PRINCIPAL DISPLAY PANEL

NDC 0143-9837-01
Penicillin V Potassium
Tablets, USP
250 mg (400,000 Units)
100 Tablets
Rx Only



PRINCIPAL DISPLAY PANEL

NDC 0143-9836-01
Penicillin V Potassium
Tablets, USP
500 mg (800,000 Units)
100 Tablets
Rx Only

1	NDC:0143-9837-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2013	
2	NDC:0143-9837-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090549	10/11/2013	

PENICILLIN V POTASSIUM

penicillin v potassium tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0143-9836
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PENICILLIN V POTASSIUM (UNII: 146T0TU1JB) (PENICILLIN V - UNII:Z61I075U2W)	PENICILLIN V	500 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	CAPSULE	**Size**	7mm
Flavor		**Imprint Code**	W;112
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0143-9836-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2013	
2	NDC:0143-9836-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2013	