

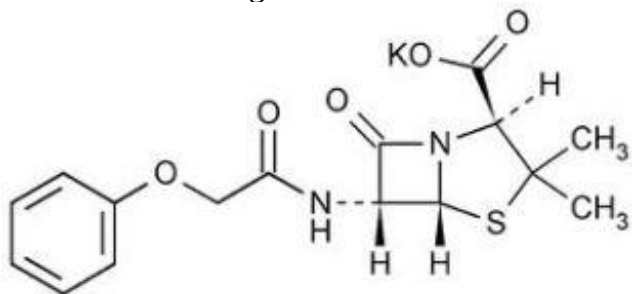
PENICILLIN V POTASSIUM- penicillin v potassium tablet
Blenheim Pharmacal, Inc.

Penicillin V Potassium Tablets, USP - 250 mg and 500 mg
R_x Only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Penicillin V Potassium Tablets, Penicillin V Potassium for Oral Solution and other antibacterial drugs, Penicillin V Potassium Tablets and Penicillin V Potassium for Oral Solution 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. Penicillin V Potassium is designated chemically as 4-Thia-1-azabicyclo [3.2.0] heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo- 6-[(phenoxyacetyl)amino]-, monopotassium salt, [2S-(2 α ,5 α ,6 β)]-. It has the following chemical structure:



The molecular formula is C₁₆H₁₇KN₂O₅S, and the molecular weight is 388.48.

Each tablet contains Penicillin V Potassium equivalent to 250 mg or 500 mg (400,000 or 800,000 units) of penicillin V.

Each Penicillin V Potassium tablet, USP, 250 mg contains 0.73 mEq (28.2 mg) of Potassium and each Penicillin V potassium tablet, USP, 500 mg contains 1.46 mEq (56.4 mg) of Potassium.

Each tablet also contains the following inactive ingredients: lactose, NF; magnesium stearate, NF; microcrystalline cellulose, NF; polyethylene glycol, NF; povidone, USP; sodium laurel sulfate, NF.

Each 5 mL when reconstituted as directed contains Penicillin V Potassium equivalent to 125 mg or 250 mg (200,000 or 400,000 units) of Penicillin V.

Each 5 mL of reconstituted Penicillin V Potassium for Oral Solution, USP, 125 mg per 5 mL contains 0.42 mEq (16.4 mg) of Potassium. Each 5 mL of reconstituted Penicillin V Potassium for Oral Solution, USP, 250 mg per 5 mL contains 0.85 mEq (32.8 mg) of Potassium.

Each 5 mL of reconstituted suspension also contains the following inactive ingredients: aspartame, NF; citric acid, USP; FD&C Red No. 40; flavors; primary taste modifier; saccharin sodium, USP; silicon dioxide, NF; sodium citrate, USP; sodium propionate, NF; sucrose, NF.

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 *N. 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 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.

INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Penicillin V Potassium Tablets, Penicillin V Potassium for Oral Solution and other antibacterial drugs, Penicillin V Potassium Tablets, and Penicillin V Potassium for Oral Solution should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antimicrobial therapy.

In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Penicillin V Potassium Tablets, USP and Penicillin V Potassium for Oral Solution, 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 with congenital heart disease or rheumatic or other acquired valvular heart disease when they undergo dental procedures and surgical procedures of the upper respiratory tract.¹ 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). Penicillin V should not be used as adjunctive prophylaxis for genitourinary instrumentation or surgery, lower-intestinal tract surgery, sigmoidoscopy, and childbirth. Since it may happen that alpha haemolytic streptococci relatively resistant to penicillin may be found when patients are receiving continuous oral penicillin for secondary prevention of rheumatic fever, prophylactic agents, other than penicillin may be chosen for these patients and prescribed in addition to their continuous rheumatic fever prophylactic regimen.

NOTE: When selecting antibiotics for the prevention of bacterial endocarditis, the physician or dentist should read the full joint statement of the American Heart Association and the American Dental Association.¹

CONTRAINDICATIONS

A previous hypersensitivity reaction to any penicillin is a contraindication.

WARNINGS

SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTIC) REACTIONS HAVE BEEN REPORTED IN PATIENTS ON PENICILLIN THERAPY. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY AND/OR A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE REACTIONS WHEN TREATED WITH CEPHALOSPORINS. BEFORE INITIATING THERAPY WITH PENICILLIN V POTASSIUM, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTION TO PENICILLINS, CEPHALOSPORINS, OR OTHER ALLERGENS. IF AN ALLERGIC REACTION OCCURS, PENICILLIN V POTASSIUM SHOULD BE DISCONTINUED AND APPROPRIATE THERAPY INSTITUTED. **SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE. OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS INDICATED.**

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Penicillin V Potassium Tablets and Penicillin V Potassium for Oral Solution, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may cause colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS

General

Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma.

Prescribing Penicillin V Potassium Tablets and Penicillin V Potassium for Oral Solution in the absence of a proven or strongly suspected bacterial infection of 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.

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

In streptococcal infections, therapy must be sufficient to eliminate the organism (ten-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.

Oral Solutions contain aspartame. Phenylketonurics: Both the 125 mg and 250 mg Oral Solutions contain phenylalanine 4.5 mg per 5 mL.

Information for Patients

Patients should be counseled that antibacterial drugs, including Penicillin V Potassium Tablets and Penicillin V Potassium for Oral Solution should only be used to treat bacterial infections. They do not treat viral infections (e.g. the common cold).

When Penicillin V Potassium Tablets or Penicillin V Potassium Oral Solution 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:

- (i) Decrease the effectiveness of the immediate treatment, and
- (ii) Increase the likelihood that bacteria will develop resistance and will not be treatable by the antibacterial drug product 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 sickness-like 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.

DOSAGE AND ADMINISTRATION

The dosage of penicillin V potassium tablets and penicillin V potassium for oral solution should be determined according to the sensitivity of the causative microorganisms and the severity of the 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 - mild to moderately severe - of the upper respiratory tract and including scarlet fever and erysipelas: 125 mg to 250 mg (200,000 to 400,000 units) every 6 to 8 hours for 10 days.

Pneumococcal infections - mild to moderately severe - of the respiratory tract, including otitis media: 250 mg to 500 mg (400,000 to 800,000 units) every 6 hours until the patient has been afebrile for at least 2 days.

Staphylococcal infections - mild infections of skin and soft tissue (culture and sensitivity tests should be performed): 250 mg to 500 mg (400,000 to 800,000 units) every 6 to 8 hours.

Fusospirochetosis (Vincent's infection) of the oropharynx. Mild to moderately severe infections: 250 mg to 500 mg (400,000 to 800,000 units) every 6 to 8 hours.

For the prevention of recurrence following rheumatic fever and/or chorea: 125 mg to 250 mg (200,000 to 400,000 units) twice daily on a continuing basis.

For prophylaxis against bacterial endocarditis¹ in patients with congenital heart disease or rheumatic or other acquired valvular heart disease when undergoing dental procedures or surgical procedures of the upper respiratory tract: 2 grams of penicillin V (1 gram for children under 60 lbs) 1 hour before the procedure, and then 1 gram (500 mg for children under 60 lbs) 6 hours later.

Directions for preparing oral solution

Prepare solution at the time of dispensing by adding the water in two portions to the bottle as follows: Loosen powder by tapping the bottle, add about half the water, and shake well. Add the remaining water and shake well to complete solution. Each teaspoon (5 mL) will contain Penicillin V Potassium equivalent to 125 mg or 250 mg of Penicillin V.

<u>Product</u>	<u>Bottle Size</u>	<u>Amount of water required for reconstitution</u>
125 mg/5 mL	100 mL	65 mL
	200 mL	127 mL
250 mg/5 mL	100 mL	65 mL
	200 mL	127 mL

Note: Shake the oral solution well before using.

Store the reconstituted solution in a refrigerator. Discard any unused portion after 14 days. Keep the bottle tightly closed.

HOW SUPPLIED

Penicillin V Potassium Tablets, USP 250 mg (400,000 units) - White, oval, biconvex tablets engraved S20.

Bottles of 20 (NDC 10544-296-20)

Bottles of 28 (NDC 10544-296-28)

Bottles of 30 (NDC 10544-296-30)

Bottles of 40 (NDC 10544-296-40)

Penicillin V Potassium Tablets, USP 500 mg (800,000 units) - White, oval, biconvex tablets engraved S21.

Bottles of 20 (NDC 10544-297-20)

Bottles of 28 (NDC 10544-297-28)

Bottles of 30 (NDC 10544-297-30)

Bottles of 40 (NDC 10544-297-40)

Bottles of 73 (NDC 10544-297-73)

Storage and Handling

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Keep tightly closed. Protect from moisture.

REFERENCE

¹American Heart Association, 1984.

Prevention of bacterial endocarditis.

Circulation 70 (6): 1123A - 1127A.

Manufactured for:

DAVA Pharmaceuticals, Inc.

Fort Lee, NJ 07024, USA

by:

STADA Production Ireland Ltd.

Clonmel, Ireland.

Marketed/ Packaged by:

Blenheim Pharmacal, Inc.

North Blenheim, NY 12131, (USA)

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL



NDC 10544-296-20

PENICILLIN V POTASSIUM

TABLETS, USP

Equivalent to **250 mg**

(800,000 units) Penicillin V.

20 tablets Rx Only

This is a bulk package, not intended for household use.

Dispense in a tight container as defined in the USP.

Usual Dosage - 250 to 500 mg (400,000 to 800,000 units)

every 6 to 8 hours. See package insert.

PHARMACY STOCK PACKAGE.

Store at 20°C to 25°C (68° to 77°F)

[See USP Controlled Room Temperature].

Keep tightly closed. Protect from moisture.

Manufactured for:

DAVA Pharmaceuticals, Inc.

Fort Lee, NJ 07024, USA

by:

STADA Production Ireland Ltd.

Clonmel, Ireland.

Marketed/ Packaged by:

Blenheim Pharmacal, Inc.

North Blenheim, NY 12131, (USA)

Rev. 04/10 0201G021

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC: 10544-297-30 LCN# 000
MFG: 67253-201-50 Rev. 3

Penicillin V Potassium Tablets, USP 500mg
30 Tablets
Rx Only

Dosage: See package insert
Store at controlled room temperature
20°-25°C (68°-77°F)

Store in a tight, light-resistant container (See USP). Keep out of the reach of children.

Protect from moisture.
Each tablet contains 500mg equivalent to 800,000 units Penicillin V

Mfg: DAVA Pharmaceuticals, Inc.
Packaged By: Blenheim Pharmacal, Inc., North Blenheim, NY 12131
Lot #: BP00000000
Exp. Date: 00/00/0000

1054429730+BP00000000+0000

Penicillin V Potassium Tablets, USP 500mg
30 Tablets
NDC: 10544-297-30 MFG: 67253-201-50
Lot #: BP00000000 Exp. Date: 00/00/0000

Penicillin V Potassium Tablets, USP 500mg
30 Tablets
NDC: 10544-297-30 MFG: 67253-201-50
Lot #: BP00000000 Exp. Date: 00/00/0000

Penicillin V Potassium Tablets, USP 500mg
30 Tablets
NDC: 10544-297-30 MFG: 67253-201-50
Lot #: BP00000000 Exp. Date: 00/00/0000

Penicillin V Potassium Tablets, USP 500mg
30 Tablets
NDC: 10544-297-30 MFG: 67253-201-50
Lot #: BP00000000 Exp. Date: 00/00/0000

PEEL HERE

PEEL HERE

NDC 10544-297-30

PENICILLIN V POTASSIUM
TABLETS, USP

Equivalent to **500 mg**

(800,000 units) Penicillin V.

30 tablets Rx Only

This is a bulk package, not intended for household use.

Dispense in a tight container as defined in the USP.

Usual Dosage - 250 to 500 mg (400,000 to 800,000 units)

every 6 to 8 hours. See package insert.

PHARMACY STOCK PACKAGE.

Store at 20°C to 25°C (68° to 77°F)

[See USP Controlled Room Temperature].

Keep tightly closed. Protect from moisture.

Manufactured for:

DAVA Pharmaceuticals, Inc.

Fort Lee, NJ 07024, USA

by:

STADA Production Ireland Ltd.

Clonmel, Ireland.

Marketed/ Packaged by:

Blenheim Pharmacal, Inc.

North Blenheim, NY 12131, (USA)

Rev. 04/10 0201G021 Rev. 01/10

0203J021

PENICILLIN V POTASSIUM

penicillin v potassium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:10544- 296(NDC:67253-200)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PENICILLIN V POTASSIUM (PENICILLIN V)	PENICILLIN V	250 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	

POVIDONES				
SODIUM LAURYL SULFATE				
POLYETHYLENE GLYCOLS				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	14mm	
Flavor		Imprint Code	S20	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10544-296-20	20 in 1 BOTTLE		
2	NDC:10544-296-28	28 in 1 BOTTLE		
3	NDC:10544-296-30	30 in 1 BOTTLE		
4	NDC:10544-296-40	40 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA062936	09/09/2009		

PENICILLIN V POTASSIUM			
penicillin v potassium tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:10544-297(NDC:67253-201)
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PENICILLIN V POTASSIUM (PENICILLIN V)		PENICILLIN V	500 mg
Inactive Ingredients			
Ingredient Name			Strength
LACTOSE			
MAGNESIUM STEARATE			
CELLULOSE, MICROCRYSTALLINE			
POVIDONES			
SODIUM LAURYL SULFATE			
POLYETHYLENE GLYCOLS			

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	16 mm
Flavor		Imprint Code	S21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10544-297-20	20 in 1 BOTTLE		
2	NDC:10544-297-28	28 in 1 BOTTLE		
3	NDC:10544-297-30	30 in 1 BOTTLE		
4	NDC:10544-297-40	40 in 1 BOTTLE		
5	NDC:10544-297-73	73 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062935	12/29/2009	

Labeler - Blenheim Pharmacal, Inc. (171434587)**Establishment**

Name	Address	ID/FEI	Business Operations
Blenheim Pharmacal, Inc.		171434587	REPACK(10544-296, 10544-297), RELABEL(10544-296, 10544-297)

Revised: 12/2013

Blenheim Pharmacal, Inc.