Descargar Fichas Tecnicas

Santiago De Jesus Castillo Gonzalez

Calle 15 65-B # 221 X 128
Fracc Yucalpetén C.p 97238
Mérida Yuc.
Cel: 9999-109946

UROLOGÍA

1. Bethanechol

2. Potassium Citrate

3. Fludrocortisone

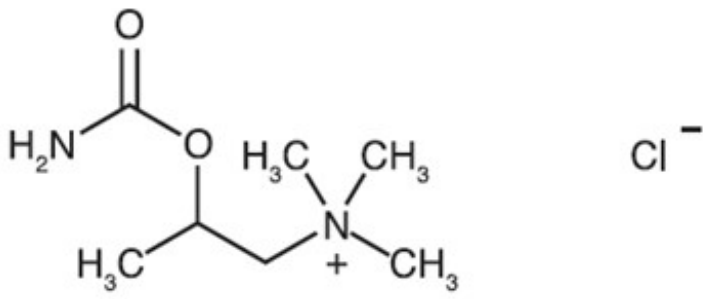
BETHANECHOL CHLORIDE- bethanechol chloride tablet
Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc.

Bethanechol Chloride Tablets, USP
Rx only

DESCRIPTION

Bethanechol chloride, a cholinergic agent, is a synthetic ester which is structurally and pharmacologically related to acetylcholine.

It is designated chemically as 2-[(aminocarbonyl)oxy]-*N, N, N,*-trimethyl-1-propanaminium chloride. Its molecular formula is $C_7H_{17}ClN_2O_2$ and its structural formula is:



It is a white, hygroscopic crystalline powder having a slight amine-like odor, freely soluble in water, and has a molecular weight of 196.68.

Each tablet for oral administration contains 5 mg, 10 mg, 25 mg or 50 mg bethanechol chloride, USP. Tablets also contain the following inactive ingredients: lactose monohydrate, silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and povidone.

CLINICAL PHARMACOLOGY

Bethanechol chloride acts principally by producing the effects of stimulation of the parasympathetic nervous system. It increases the tone of the detrusor urinae muscle, usually producing a contraction sufficiently strong to initiate micturition and empty the bladder. It stimulates gastric motility, increases gastric tone and often restores impaired rhythmic peristalsis.

Stimulation of the parasympathetic nervous system releases acetylcholine at the nerve endings. When spontaneous stimulation is reduced and therapeutic intervention is required, acetylcholine can be given, but it is rapidly hydrolyzed by cholinesterase and its effects are transient. Bethanechol chloride is not destroyed by cholinesterase and its effects are more prolonged than those of acetylcholine.

Effects on the GI and urinary tracts sometimes appear within 30 minutes after oral

administration of bethanechol chloride, but more often 60 to 90 minutes are required to reach maximum effectiveness. Following oral administration, the usual duration of action of bethanechol is one hour, although large doses (300 to 400 mg) have been reported to produce effects for up to six hours. Subcutaneous injection produces a more intense action on bladder muscle than does oral administration of the drug.

Because of the selective action of bethanechol, nicotinic symptoms of chlolinergic stimulation are usually absent or minimal when orally or subcutaneously administered in therapeutic doses, while muscarinic effects are prominent. Muscarinic effects usually occur within 5 to 15 minutes after subcutaneous injection, reach a maximum in 15 to 30 minutes, and disappear within two hours. Doses that stimulate micturition and defecation and increase peristalsis do not ordinarily stimulate ganglia or voluntary muscles. Therapeutic test doses in normal human subjects have little effect on heart rate, blood pressure or peripheral circulation.

Bethanechol chloride does not cross the blood-brain barrier because of its charged quaternary amine moiety. The metabolic rate and mode of excretion of the drug have not been elucidated.

A clinical study (Diokno, A.C.; Lapides, J.; Urol 10: 23-24, July 1977) was conducted on the relative effectiveness of oral and subcutaneous doses of bethanechol chloride on the stretch response of bladder muscle in patients with urinary retention. Results showed that 5 mg of the drug given subcutaneously stimulated a response that was more rapid in onset and of larger magnitude than an oral dose of 50 mg, 100 mg, or 200 mg. All the oral doses, however, had a longer duration of effect than the subcutaneous dose. Although the 50 mg oral dose caused little change in intravesical pressure in this study, this dose has been found in other studies to be clinically effective in the rehabilitation of patients with decompensated bladders.

INDICATIONS AND USAGE

Bethanechol chloride is indicated for the treatment of acute postoperative and postpartum nonobstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention.

CONTRAINDICATIONS

Hypersensitivity to bethanechol chloride tablets, hyperthyroidism, peptic ulcer, latent or active bronchial asthma, pronounced bradycardia or hypotension, vasomotor instability, coronary artery disease, epilepsy and parkinsonism.

Bethanechol chloride should not be employed when the strength or integrity of the gastrointestinal or bladder wall is in question, or in the presence of mechanical obstruction; when increased muscular activity of the gastrointestinal tract or urinary bladder might prove harmful, as following recent urinary bladder surgery, gastrointestinal resection and anastomosis, or when there is possible gastrointestinal obstruction; in bladder neck obstruction, spastic gastrointestinal disturbances, acute inflammatory lesions of the gastrointestinal tract, or peritonitis; or in marked vagotonia.

PRECAUTIONS

General

In urinary retention, if the sphincter fails to relax as bethanechol contracts the bladder, urine may be forced up the ureter into the kidney pelvis. If there is bacteriuria, this may cause reflux infection.

Information for Patients

Bethanechol chloride tablets should preferably be taken one hour before or two hours after meals to avoid nausea or vomiting. Dizziness, lightheadedness or fainting may occur, especially when getting up from a lying or sitting position.

Drug Interactions

Special care is required if this drug is given to patients receiving ganglion blocking compounds because a critical fall in blood pressure may occur. Usually, severe abdominal symptoms appear before there is such a fall in the blood pressure.

Carcinogeneis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the effects upon fertility, mutagenic or carcinogenic potential of bethanechol chloride.

Pregnancy

Teratogenic effects: Pregnancy Category C

Animal reproduction studies have not been conducted with bethanechol chloride. It is also not known whether bethanechol chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Bethanechol chloride should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is secreted in human milk. Because many drugs are secreted in human milk and because of the potential for serious adverse reactions from bethanechol chloride in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse reactions are rare following oral administration of bethanechol, but are more common following subcutaneous injection. Adverse reactions are more likely to occur when dosage is increased.

The following adverse reactions have been observed: *Body as a Whole:* malaise; *Digestive:* abdominal cramps or discomfort, colicky pain, nausea and belching, diarrhea, borborygmi, salivation; *Renal:* urinary urgency; *Nervous System:* headache; *Cardiovascular:* a fall in blood pressure with reflex tachycardia, vasomotor response; *Skin:* flushing producing a feeling of warmth, sensation of heat about the face, sweating; *Respiratory:* bronchial constriction, asthmatic attacks; *Special Senses:* lacrimation, miosis.

Causal Relationship Unknown: The following adverse reactions have been reported, and a causal relationship to therapy with bethanechol has not been established: *Body as a whole:* malaise; *Nervous System:* seizures.

To report SUSPECTED ADVERSE REACTIONS, contact Avet Pharmaceuticals Inc. at 1-866-901-DRUG (3784) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Early signs of overdosage are abdominal discomfort, salivation, flushing of the skin ("hot feeling"), sweating, nausea, and vomiting.

Atropine Sulfate is a specific antidote. The recommended dose for adults is 0.6 mg. Repeat doses can be given every two hours, according to clinical response. The recommended dosage in infants and children up to 12 years of age is 0.01 mg/kg (to a maximum single dose of 0.4 mg) repeated every two hours as needed until the desired effect is obtained or adverse effects of atropine preclude further usage. Subcutaneous injection of atropine is preferred except in emergencies when the intravenous route may be employed.

The oral LD_{50} of bethanechol chloride is 1510 mg/kg in the mouse.

DOSAGE AND ADMINISTRATION

Dosage must be individualized, depending on the type and severity of the condition to be treated.

Preferably give the drug when the stomach is empty. If taken soon after eating, nausea and vomiting may occur.

The usual adult oral dose ranges from 10 to 50 mg three or four times a day. The minimum effective dose is determined by giving 5 to 10 mg initially and repeating the same amount at hourly intervals until satisfactory response occurs, or until a maximum of 50 mg has been given. The effects of the drug sometimes appear within 30 minutes and are usually maximal within 60 to 90 minutes. The drug effects persist for about one hour.

If necessary, the effects of the drug can be abolished promptly by atropine (see **OVERDOSAGE**).

HOW SUPPLIED

Bethanechol Chloride Tablets, USP

5 mg - White, round, flat-faced beveled edge tablets debossed "934" on one side and score line on the other side.

NDC 23155-934-01 Bottles of 100

10 mg - White, round, flat-faced beveled edge tablets debossed "935" on one side and score line on the other side.

NDC 23155-935-01 Bottles of 100

25 mg - White, round, flat-faced beveled edge tablets debossed “936” on one side and score line on the other side.

NDC 23155-936-01 Bottles of 100

50 mg - White, round, flat-faced beveled edge tablets debossed “937” on one side and score line on the other side.

NDC 23155-937-01 Bottles of 100

Dispense in a tight container as defined in the USP.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Distributed by:

Avet Pharmaceuticals Inc.

East Brunswick, NJ 08816

1-866-901-DRUG (3784)

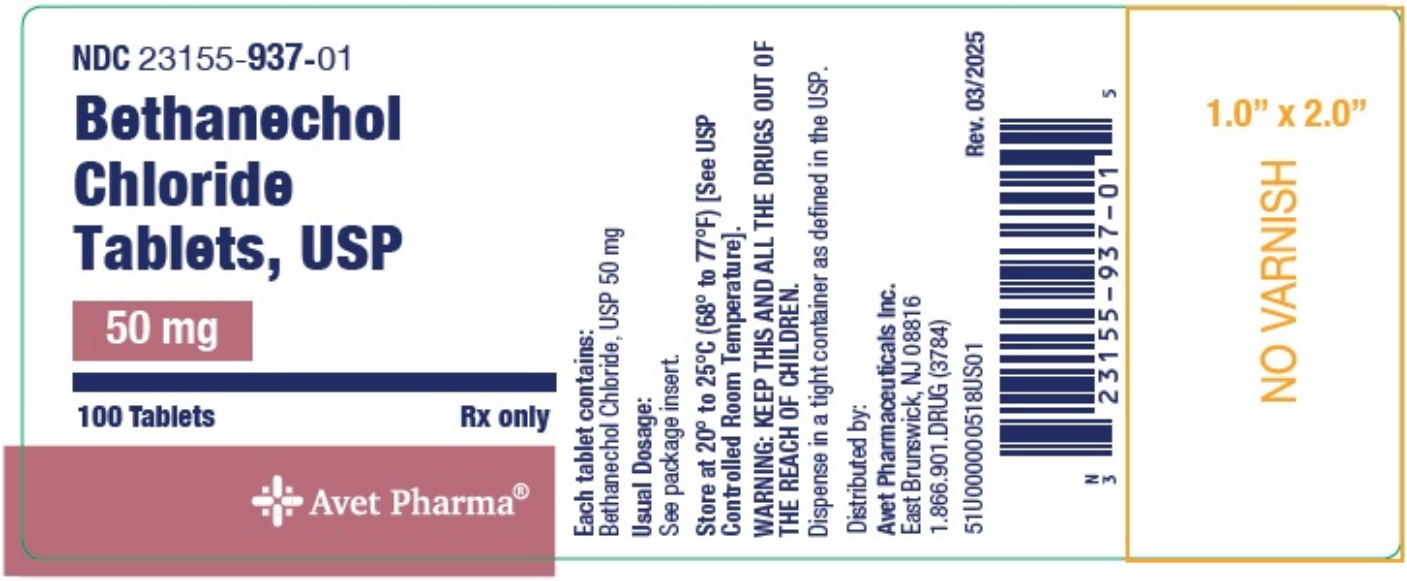
Revised: 03/2025

PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL



BETHANECHOL CHLORIDE

bethanechol chloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23155-934
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BETHANECHOL CHLORIDE (UNII: H4QBZ2LO84) (BETHANECHOL - UNII:004F72P8F4)	BETHANECHOL CHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	934
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:23155-934-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091256	06/30/2025	

BETHANECHOL CHLORIDE

bethanechol chloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23155-935
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BETHANECHOL CHLORIDE (UNII: H4QBZ2LO84) (BETHANECHOL - UNII:004F72P8F4)	BETHANECHOL CHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	935
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:23155-935-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091256	06/30/2025	

BETHANECHOL CHLORIDE

bethanechol chloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23155-936
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BETHANECHOL CHLORIDE (UNII: H4QBZ2LO84) (BETHANECHOL - UNII:004F72P8F4)	BETHANECHOL CHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	936
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:23155-936-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091256	06/30/2025	

BETHANECHOL CHLORIDE

bethanechol chloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23155-937
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETHANECHOL CHLORIDE (UNII: H4QBZ2LO84) (BETHANECHOL - UNII:004F72P8F4)	BETHANECHOL CHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	937
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23155-937-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091256	06/30/2025	

Labeler - Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc. (780779901)

Registrant - Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc. (189630168)

Establishment

Name	Address	ID/FEI	Business Operations
Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc.		189630168	analysis(23155-934, 23155-935, 23155-936, 23155-937) , label(23155-934, 23155-935, 23155-936, 23155-937) , manufacture(23155-934, 23155-935, 23155-936, 23155-937) , pack(23155-934, 23155-935, 23155-936, 23155-937)

POTASSIUM CITRATE AND CITRIC ACID- potassium citrate and citric acid monohydrate solution
Pharmaceutical Associates, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Potassium Citrate and Citric Acid Oral Solution USP

Rx ONLY

DESCRIPTION

Potassium Citrate and Citric Acid Oral Solution USP is a stable and pleasant-tasting oral systemic alkalizer containing potassium citrate and citric acid in a sugar-free, non-alcoholic base.

Potassium Citrate and Citric Acid Oral Solution USP contains in each teaspoonful (5 mL):

POTASSIUM CITRATE Monohydrate 1100 mg

CITRIC ACID Monohydrate 334 mg

Each mL contains 2 mEq potassium ion and is equivalent to 2 mEq bicarbonate (HCO_3).

Inactive Ingredients: FD&C Red No. 40, flavoring, polyethylene glycol, propylene glycol, purified water, sodium benzoate, and sorbitol solution.

ACTIONS

Potassium citrate is absorbed and metabolized to potassium bicarbonate, thus acting as a systemic alkalizer. The effects are essentially those of chlorides before absorption and those of bicarbonates subsequently. Oxidation is virtually complete so that less than 5% of the potassium citrate is excreted in the urine unchanged.

INDICATIONS AND USAGE

Potassium Citrate and Citric Acid Oral Solution USP is an effective alkalinizing agent useful in those conditions where long-term maintenance of an alkaline urine is desirable, such as in patients with uric acid and cystine calculi of the urinary tract, especially when the administration of sodium salts is undesirable or contraindicated. In addition, it is a valuable adjuvant when administered with uricosuric agents in gout therapy, since urates tend to crystallize out of an acid urine. It is also effective in correcting the acidosis of certain renal tubular disorders where the administration of potassium citrate may be preferable. This product is highly concentrated, and when administered after meals and before bedtime, allows one to maintain an alkaline urinary pH around the clock, usually without the necessity of a 2 A.M. dose. This product alkalinizes the urine without producing a systemic alkalosis in recommended dosage. It is highly palatable, pleasant tasting and tolerable, even when administered for long periods. Potassium citrate does not neutralize the gastric juice or disturb digestion.

CONTRAINDICATIONS

Severe renal impairment with oliguria or azotemia, untreated Addison's disease, adynamia episodica hereditaria, acute dehydration, heat cramps, anuria, severe myocardial damage, and hyperkalemia from any cause.

WARNINGS

Large doses may cause hyperkalemia and alkalosis, especially in the presence of renal disease. Concurrent administration of potassium-containing medication, potassium-sparing diuretics, angiotensin-converting enzyme (ACE) inhibitors, or cardiac glycosides may lead to toxicity.

PRECAUTIONS

Should be used with caution by patients with low urinary output unless under the supervision of a physician. As with all liquids containing a high concentration of potassium, patients should be directed to dilute adequately with water to minimize the possibility of gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations; and preferably, to take each dose after meals to avoid saline laxative effect.

ADVERSE REACTIONS

Potassium Citrate and Citric Acid Oral Solution USP is generally well tolerated without any unpleasant side effects when given in recommended doses to patients with normal renal function and urinary output. However, as with any alkalinizing agent, caution must be used in certain patients with abnormal renal mechanisms to avoid development of hyperkalemia or alkalosis. Potassium intoxication causes listlessness, weakness, mental confusion, tingling of extremities, and other symptoms associated with a high concentration of potassium in the serum. Periodic determinations of serum electrolytes should be carried out in those patients with renal disease in order to avoid these complications. Hyperkalemia may exhibit the following electrocardiographic abnormalities: Disappearance of the P wave, widening and slurring of QRS complex, changes of the S-T segment, tall peaked T waves, etc.

OVERDOSAGE

The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired, hyperkalemia can result (see Contraindications and Warnings). Hyperkalemia, when detected, must be treated immediately because lethal levels can be reached in a few hours.

TREATMENT OF HYPERKALEMIA

Should hyperkalemia occur, treatment measures include the following: (1) Elimination of

foods or medications containing potassium. (2) The intravenous administration of 300 to 500 mL/hr of dextrose solution (10 to 25%), containing 10 units of insulin/20 gm dextrose. (3) The use of exchange resins, hemodialysis, or peritoneal dialysis. In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the plasma potassium concentration can produce digitalis toxicity.

DOSAGE AND ADMINISTRATION

Potassium Citrate and Citric Acid Oral Solution USP should be taken diluted in water according to directions, followed by additional water, if desired. Palatability is enhanced if chilled before taking.

Usual Adult Dose

3 to 6 teaspoonfuls (15 to 30 mL), diluted with 1 glass of water, after meals and at bedtime, or as directed by a physician.

Usual Pediatric Dose

1 to 3 teaspoonfuls (5 to 15 mL), diluted with 1/2 glass of water, after meals and at bedtime, or as directed by a physician.

Usual Dosage Range

2 to 3 teaspoonfuls (10 to 15 mL), diluted with a glassful of water, taken four times a day. Potassium Citrate and Citric Acid Oral Solution USP, diluted with a glassful of water, taken four times a day will usually maintain a urinary pH of 7.0-7.6 throughout most of the 24 hours without unpleasant side effects. To check urinary pH, HYDRION Paper (pH 6.0-8.0) or NITRAZINE Paper (pH 4.5-7.5) are available and easy to use.

HOW SUPPLIED

Potassium Citrate and Citric Acid Oral Solution USP (clear pink to red colored; berry-citrus flavored) is supplied in the following oral dosage form:

NDC 0121-0676-16: 16 fl oz (473 mL) bottle

STORAGE

Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F). Protect from excessive heat and freezing.

MANUFACTURED BY

Pharmaceutical Associates, Inc. Greenville, SC 29605
www.paipharma.com

R03/17

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0676-16

Potassium Citrate
and Citric Acid
Oral Solution USP
1100 mg/334 mg per 5 mL

A SUGAR-FREE SYSTEMIC ALKALIZER

Each teaspoonful (5 mL) contains:
Potassium Citrate Monohydrate.....1100 mg
Citric Acid Monohydrate.....334 mg

Each mL contains 2 mEq Potassium Ion, and is equivalent to 2 mEq Bicarbonate (HCO_3).

Rx ONLY

16 fl oz (473 mL)

Pharmaceutical
Associates, Inc.
Greenville, SC 29605

INDICATIONS AND USAGE: Potassium Citrate and Citric Acid Oral Solution USP is a stable and pleasant-tasting oral systemic alkalizer. It is effective for long-term maintenance of an alkaline urine, especially when the administration of sodium salts is undesirable or contra-indicated.

SEE ACCOMPANYING LITERATURE

DOSAGE AND ADMINISTRATION:

Usual Adult Dosage: 3 to 6 teaspoonfuls (15 to 30 mL) **DILUTED** with 1 glass of water, after meals and at bedtime, or as directed by a physician.

SHAKE WELL BEFORE USING.

STORAGE: Keep tightly closed. Store at controlled room temperature. 20° -25° C (68° -77° F). Protect from excessive heat or freezing.

Dispense in a tight, light-resistance container with a child-resistant closure.

L06761600
R08/14

POTASSIUM CITRATE AND CITRIC ACID

potassium citrate and citric acid monohydrate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-0676
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CITRATE (UNII: EE90ONI6FF) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	POTASSIUM CITRATE	1100 mg in 5 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	334 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	red	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0121-0676-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/07/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/07/1997	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0676)

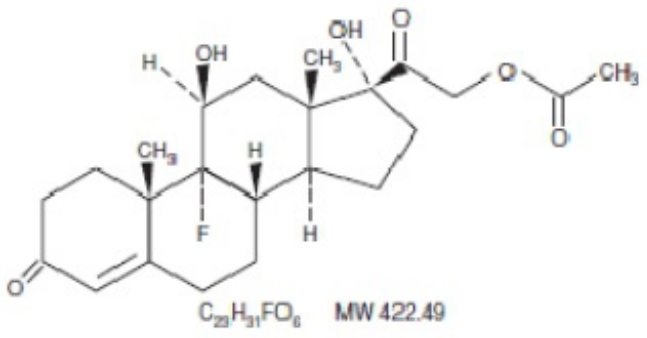
Revised: 1/2022 Pharmaceutical Associates, Inc.

FLUDROCORTISONE ACETATE- fludrocortisone acetate tablet
West-ward Pharmaceutical Corp

Fludrocortisone Acetate Tablets, USP

Description

Fludrocortisone Acetate Tablets contain fludrocortisone acetate, a synthetic adrenocortical steroid possessing very potent mineralocorticoid properties and high glucocorticoid activity; it is used only for its mineralocorticoid effects. The chemical name for fludrocortisone acetate is 9-fluoro-11ß,17,21-trihydroxypregn-4-ene-3,20-dione 21-acetate; its structural formula is:



Fludrocortisone Acetate Tablets are available for oral administration as scored tablets providing 0.1 mg fludrocortisone acetate per tablet. Inactive ingredients: anhydrous lactose, corn starch, lactose monohydrate, magnesium stearate, sugar, and talc.

Clinical Pharmacology

Corticosteroids are thought to act, at least in part, by controlling the rate of synthesis of proteins. Although there are a number of instances in which the synthesis of specific proteins is known to be induced by corticosteroids, the links between the initial actions of the hormones and the final metabolic effects have not been completely elucidated.

The physiologic action of fludrocortisone acetate is similar to that of hydrocortisone. However, the effects of fludrocortisone acetate, particularly on electrolyte balance, but also on carbohydrate metabolism, are considerably heightened and prolonged. Mineralocorticoids act on the distal tubules of the kidney to enhance the reabsorption of sodium ions from the tubular fluid into the plasma; they increase the urinary excretion of both potassium and hydrogen ions. The consequence of these three primary effects together with similar actions on cation transport in other tissues appear to account for the entire spectrum of physiological activities that are characteristic of mineralocorticoids. In small oral doses, fludrocortisone acetate produces marked sodium retention and increased urinary potassium excretion. It also causes a rise in blood pressure, apparently because of these effects on electrolyte levels.

In larger doses, fludrocortisone acetate inhibits endogenous adrenal cortical secretion, thymic activity, and pituitary corticotropin excretion; promotes the deposition of liver glycogen; and, unless protein intake is adequate, induces negative nitrogen balance.

The approximate plasma half-life of fludrocortisone (fluorohydrocortisone) is 3.5 hours or more and the biological half-life is 18 to 36 hours.

Indications and Usage

Fludrocortisone Acetate Tablets, 0.1 mg are indicated as partial replacement therapy for primary and secondary adrenocortical insufficiency in Addison's disease and for the treatment of salt-losing adrenogenital syndrome.

Contraindications

Corticosteroids are contraindicated in patients with systemic fungal infections and in those with a history of possible or known hypersensitivity to these agents.

Warnings

BECAUSE OF ITS MARKED EFFECT ON SODIUM RETENTION, THE USE OF FLUDROCORTISONE ACETATE IN THE TREATMENT OF CONDITIONS OTHER THAN THOSE INDICATED HEREIN IS NOT ADVISED.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. If an infection occurs during fludrocortisone acetate therapy, it should be promptly controlled by suitable antimicrobial therapy.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. However, since fludrocortisone acetate is a potent mineralocorticoid, both the dosage and salt intake should be carefully monitored in order to avoid the development of hypertension, edema, or weight gain. **Periodic checking of serum electrolyte levels is advisable during prolonged therapy; dietary salt restriction and potassium supplementation may be necessary.** All corticosteroids increase calcium excretion.

Patients should not be vaccinated against smallpox while on corticosteroid therapy. Other immunization procedures should not be undertaken in patients who are on corticosteroids, especially on high dose, because of possible hazards of neurological complications and a lack of antibody response.

The use of Fludrocortisone Acetate Tablets in patients with active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary since reactivation of the disease may occur. During prolonged corticosteroid therapy these patients should receive chemoprophylaxis.

Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chicken pox and measles, for example, can have a more serious or even fatal course in children on immunosuppressant corticosteroids. In such children, or in adults who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chicken pox develops, treatment with antiviral agents may be considered.

Precautions

General

Adverse reactions to corticosteroids may be produced by too rapid withdrawal or by continued use of

large doses.

To avoid drug-induced adrenal insufficiency, supportive dosage may be required in times of stress (such as trauma, surgery, or severe illness) both during treatment with fludrocortisone acetate and for a year afterwards.

There is an enhanced corticosteroid effect in patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

The lowest possible dose of corticosteroid should be used to control the condition being treated. A gradual reduction in dosage should be made when possible.

Psychic derangements may appear when corticosteroids are used. These may range from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Existing emotional instability or psychotic tendencies may also be aggravated by corticosteroids.

Aspirin should be used cautiously in conjunction with corticosteroids in patients with hypoprothrombinemia.

Corticosteroids should be used with caution in patients with nonspecific ulcerative colitis if there is a probability of impending perforation, abscess, or other pyogenic infection. Corticosteroids should also be used cautiously in patients with diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis, and myasthenia gravis.

Information for Patients

The physician should advise the patient to report any medical history of heart disease, high blood pressure, or kidney or liver disease and to report current use of any medicines to determine if these medicines might interact adversely with fludrocortisone acetate (see **Drug Interactions**).

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chicken pox or measles and, if exposed, to obtain medical advice.

The patient’s understanding of his steroid-dependent status and increased dosage requirement under widely variable conditions of stress is vital. Advise the patient to carry medical identification indicating his dependence on steroid medication and, if necessary, instruct him to carry an adequate supply of medication for use in emergencies.

Stress to the patient the importance of regular follow-up visits to check his progress and the need to promptly notify the physician of dizziness, severe or continuing headaches, swelling of feet or lower legs, or unusual weight gain.

Advise the patient to use the medicine only as directed, to take a missed dose as soon as possible, unless it is almost time for the next dose, and not to double the next dose.

Inform the patient to keep this medication and all drugs out of the reach of children.

Laboratory Tests

Patients should be monitored regularly for blood pressure determinations and serum electrolyte determinations (see **WARNINGS**).

Drug Interactions

When administered concurrently, the following drugs may interact with adrenal corticosteroids.

Amphotericin B or potassium-depleting diuretics (benzothiadiazines and related drugs, ethacrynic acid and furosemide)—enhanced hypokalemia. Check serum potassium levels at frequent intervals; use potassium supplements if necessary (see **WARNINGS**).

Digitalis glycosides—enhanced possibility of arrhythmias or digitalis toxicity associated with

hypokalemia. Monitor serum potassium levels; use potassium supplements if necessary.

Oral anticoagulants—decreased prothrombin time response. Monitor prothrombin levels and adjust anticoagulant dosage accordingly.

Antidiabetic drugs (oral agents and insulin)—diminished antidiabetic effect. Monitor for symptoms of hyperglycemia; adjust dosage of antidiabetic drug upward if necessary.

Aspirin—increased ulcerogenic effect; decreased pharmacologic effect of aspirin. Rarely salicylate toxicity may occur in patients who discontinue steroids after concurrent high-dose aspirin therapy. Monitor salicylate levels or the therapeutic effect for which aspirin is given; adjust salicylate dosage accordingly if effect is altered (see **PRECAUTIONS**, **General**).

Barbiturates, phenytoin, or rifampin—increased metabolic clearance of fludrocortisone acetate because of the induction of hepatic enzymes. Observe the patient for possible diminished effect of steroid and increase the steroid dosage accordingly.

Anabolic steroids (particularly C-17 alkylated androgens such as oxymetholone, methandrostenolone, norethandrolone, and similar compounds)—enhanced tendency toward edema. Use caution when giving these drugs together, especially in patients with hepatic or cardiac disease.

Vaccines—neurological complications and lack of antibody response (see **WARNINGS**).

Estrogen—increased levels of corticosteroid-binding globulin, thereby increasing the bound (inactive) fraction; this effect is at least balanced by decreased metabolism of corticosteroids. When estrogen therapy is initiated, a reduction in corticosteroid dosage may be required, and increased amounts may be required when estrogen is terminated.

Drug/Laboratory Test Interactions

Corticosteroids may affect the nitrobluetetrazolium test for bacterial infection and produce false-negative results.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Adequate studies have not been performed in animals to determine whether fludrocortisone acetate has carcinogenic or mutagenic activity or whether it affects fertility in males or females.

Pregnancy

Teratogenic Effects: Category C

Adequate animal reproduction studies have not been conducted with fludrocortisone acetate. However, many corticosteroids have been shown to be teratogenic in laboratory animals at low doses. Teratogenicity of these agents in man has not been demonstrated. It is not known whether fludrocortisone acetate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Fludrocortisone acetate should be given to a pregnant woman only if clearly needed.

Nonteratogenic Effects

Infants born of mothers who have received substantial doses of fludrocortisone acetate during pregnancy should be carefully observed for signs of hypoadrenalism.

Maternal treatment with corticosteroids should be carefully documented in the infant’s medical records to assist in follow up.

Nursing Mothers

Corticosteroids are found in the breast milk of lactating women receiving systemic therapy with these agents. Caution should be exercised when fludrocortisone acetate is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

Adverse Reactions

Most adverse reactions are caused by the drug's mineralocorticoid activity (retention of sodium and water) and include hypertension, edema, cardiac enlargement, congestive heart failure, potassium loss, and hypokalemic alkalosis.

When fludrocortisone is used in the small dosages recommended, the glucocorticoid side effects often seen with cortisone and its derivatives are not usually a problem; however the following untoward effects should be kept in mind, particularly when fludrocortisone is used over a prolonged period of time or in conjunction with cortisone or a similar glucocorticoid.

Musculoskeletal—muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathologic fracture of long bones, and spontaneous fractures.

Gastrointestinal—peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, and ulcerative esophagitis.

Dermatologic—impaired wound healing, thin fragile skin, bruising, petechiae and ecchymoses, facial erythema, increased sweating, subcutaneous fat atrophy, purpura, striae, hyperpigmentation of the skin and nails, hirsutism, acneiform eruptions, and hives; reactions to skin tests may be suppressed.

Neurological—convulsions, increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment, vertigo, headache, and severe mental disturbances.

Endocrine—menstrual irregularities; development of the cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g., trauma, surgery, or illness); decreased carbohydrate tolerance; manifestations of latent diabetes mellitus; and increased requirements for insulin or oral hypoglycemic agents in diabetics.

Ophthalmic—posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and exophthalmos.

Metabolic—hyperglycemia, glycosuria, and negative nitrogen balance due to protein catabolism.

Allergic Reactions—allergic skin rash, maculopapular rash, and urticaria.

Other adverse reactions that may occur following the administration of a corticosteroid are necrotizing angiitis, thrombophlebitis, aggravation or masking of infections, insomnia, syncopal episodes, and anaphylactoid reactions.

Overdosage

Development of hypertension, edema, hypokalemia, excessive increase in weight, and increase in heart size are signs of overdosage of fludrocortisone acetate. When these are noted, administration of the drug should be discontinued, after which the symptoms will usually subside within several days; subsequent treatment with fludrocortisone acetate should be with a reduced dose. Muscular weakness may develop due to excessive potassium loss and can be treated by administering a potassium supplement. Regular monitoring of blood pressure and serum electrolytes can help to prevent overdosage (see **WARNINGS**).

Dosage and Administration

Dosage depends on the severity of the disease and the response of the patient. Patients should be continually monitored for signs that indicate dosage adjustment is necessary, such as remissions or exacerbations of the disease and stress (surgery, infection, trauma) (see **WARNINGS** and **PRECAUTIONS**, **General**).

Addison's Disease

In Addison's disease, the combination of Fludrocortisone Acetate Tablets with a glucocorticoid such as hydrocortisone or cortisone provides substitution therapy approximating normal adrenal activity with minimal risks of unwanted effects.

The usual dose is 0.1 mg of Fludrocortisone Acetate Tablets daily, although dosage ranging from 0.1 mg three times a week to 0.2 mg daily has been employed. In the event transient hypertension develops as a consequence of therapy, the dose should be reduced to 0.05 mg daily. Fludrocortisone Acetate Tablets are preferably administered in conjunction with cortisone (10 mg to 37.5 mg daily in divided doses) or hydrocortisone (10 mg to 30 mg daily in divided doses).

Salt-Losing Adrenogenital Syndrome

The recommended dosage for treating the salt-losing adrenogenital syndrome is 0.1 mg to 0.2 mg of Fludrocortisone Acetate Tablets daily.

How Supplied

Fludrocortisone Acetate Tablets, USP 0.1 mg are Round, White Tablets, Scored, Debossed "W" on the plain side and "46" on scored side.

Bottles of 30 tablets
Bottles of 100 tablets

Storage

Store at 20-25ºC (68-77ºF) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Manufactured by:
West-ward Pharmaceutical Corp.
Eatontown, NJ 07724

Issued January 2010

Principal Display Panel

Fludrocortisone Acetate Tablets, USP
0.1 mg/30 Tablets
NDC 0143-1246-30

FLUDROCORTISONE ACETATE

fludrocortisone acetate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0143-1246
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUDROCORTISONE ACETATE (UNII: V47IF0PVH4) (FLUDROCORTISONE - UNII:U0476M545B)	FLUDROCORTISONE ACETATE	0.1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CORN STARCH 3-E-DODECENYL SUCCINIC ANHYDRIDE MODIFIED (UNII: QG4MW19XYX)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	W;46
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0143-1246-01	100 in 1 BOTTLE		
2	NDC:0143-1246-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091302	07/22/2011	

Labeler - West-ward Pharmaceutical Corp (001230762)

Establishment

Name	Address	ID/FEI	Business Operations
West-ward Pharmaceutical Corp		001230762	MANUFACTURE

Revised: 7/2011 West-ward Pharmaceutical Corp