ALKALI-B6 SYRUP

Composition :
Each 5 ml. contains :
Potassium Citrate …… 1100mg.
Magnesium Citrate ….. 375mg.
Pyridoxine Hcl.(Vit.B6)… 20mg.

Kidney stones, is one of the most painful of the urologic disorders. Unfortunately, kidney stones are one of the most common disorders of the urinary tract. Each year, people make almost 3 million visits to health care providers and more than half a million people go to emergency rooms for kidney stone problems.
Most kidney stones pass out of the body without any intervention by a physician. Stones that cause lasting symptoms or other research advances have led to a better understanding of the many factors that promote stone formation and thus better treatments for preventing stones.
Complications may be treated by various techniques, most of which do not involve major surgery.

What is a kidney stone?

A kidney stone is a hard mass developed from crystals that separate from the urine within the urinary tract. Normally, urine contains chemicals that prevent or inhibit the crystals from forming. These inhibitors do not seem to work for everyone, however, so some people form stones. If the crystals remain tiny enough, they will travel through the urinary tract and pass out of the body in the urine without being noticed.
Kidney stones may contain various combinations of chemicals. The most common type of stone contains calcium in combination with either oxalate (**$C_2O_4^{2-}$, also written $(COO)_2^{2-}$**) or phosphate (**an inorganic chemical and a salt of phosphoric acid**). These chemicals are part of a person's normal diet and make up important parts of the body, such as bones and muscles.
A less common type of stone is caused by infection in the urinary tract. This type of stone is called a struvite or infection stone. Another type of stone, uric acid stones, are a bit less common, and cystine stones are rare.
Gallstones and kidney stones are not related. They form in different areas of the body. Someone with a gallstone is not necessarily more likely to develop kidney stones.

What causes kidney stones?

Doctors do not always know what causes a stone to form. While certain foods may promote stone formation in people who are susceptible, scientists do not believe that eating any specific food causes stones to form in people who are not susceptible.
A person with a family history of kidney stones may be more likely to develop stones. Urinary tract infections, kidney disorders such as cystic kidney diseases, and certain metabolic disorders such as hyperparathyroidism are also linked to stone formation.
In addition, more than 70 percent of people with a rare hereditary disease called renal tubular acidosis develop kidney stones.
Cystinuria and hyperoxaluria are two other rare, inherited metabolic disorders that often cause kidney stones. In cystinuria, too much of the amino acid cystine, which does not dissolve in urine, is voided, leading to the formation of stones made of cystine. In patients with hyperoxaluria, the body produces too much oxalate, a salt. When the urine contains more oxalate than can be dissolved, the crystals settle out and form stones.
Hypercalciuria is inherited, and it may be the cause of stones in more than half of patients. Calcium is absorbed from food in excess and pass out into the urine. This high level of calcium in the urine causes crystals of calcium oxalate or calcium phosphate to form in the kidneys or elsewhere in the urinary tract.
Other causes of kidney stones are hyperuricosuria, which is a disorder of uric acid metabolism; gout; excess intake of vitamin D; urinary tract infections; and blockage of the urinary tract. Certain diuretics, commonly

called water pills and calcium-based antacids may increase the risk of forming kidney stones by increasing the amount of calcium in the urine.

Calcium oxalate stones may also form in people who have chronic inflammation of the bowel or who have had an intestinal bypass operation, or ostomy surgery. As mentioned earlier, struvite stones can form in people who have had a urinary tract infection. People who take the protease inhibitor indinavir, a medicine used to treat HIV infection, may also be at increased risk of developing kidney stones.

Foods and Drinks Containing Oxalate
People prone to forming calcium oxalate stones may be asked by their doctor to limit or avoid certain foods if their urine contains an excess of oxalate.

High-oxalate foods -- higher to lower : Rhubarb**,** spinach**,** beets**,** swiss chard**,** wheat germ**,** soybean crackers**,** peanuts**,** okra**,** chocolate**,** black Indian tea**,** sweet and potatoes.

Foods that have medium amounts of oxalate may be eaten in limited amounts: Grits
Grapes**,** celery**,** green pepper**,** red raspberries**,** fruit cake**,** strawberries**,** marmalade and liver.

What are the symptoms of kidney stones?

Kidney stones often do not cause any symptoms. Usually, the first symptom of a kidney stone is extreme pain, which begins suddenly when a stone moves in the urinary tract and blocks the flow of urine. Typically, a person feels a sharp, cramping pain in the back and side in the area of the kidney or in the lower abdomen. Sometimes nausea and vomiting occur. Later, pain may spread to the groin.
If the stone is too large to pass easily, pain continues as the muscles in the wall of the narrow ureter try to squeeze the stone into the bladder. As the stone moves and the body try to push it out, blood may appear in the urine, making the urine pink. As the stone moves down the ureter, closer to the bladder, a person may feel the need to urinate more often or feel a burning sensation during urination.
If fever and chills accompany any of these symptoms, an infection may be present. In this case, a person should contact a doctor immediately.

How are kidney stones diagnosed?

Sometimes "silent" stones -- those that do not cause symptoms -- are found on x-rays taken during a general health exam. If the stones are small, they will often pass out of the body unnoticed. Often, kidney stones are found on an x-ray or ultrasound taken of someone who complains of blood in the urine or sudden pain. These diagnostic images give the doctor valuable information about the stone's size and location. Blood and urine tests help detect any abnormal substance that might promote stone formation.
The doctor may decide to scan the urinary system using a special test called a computerized tomography (CT) scan or an intravenous pyelogram (IVP). The results of all these tests help determine the proper treatment.

PREVENTING KIDNEY STONES

A person who has had more than one kidney stone may be likely to form another; so, if possible, prevention is important. To help determine their cause, the doctor will suggest laboratory tests, including urine and blood tests. The doctor will also ask about the patient's medical history, occupation, and eating habits. If a stone has been removed, or if the patient has passed a stone and saved it, a stone analysis by the laboratory may help the doctor in planning treatment.
The doctor may ask the patient to collect urine for 24 hours after a stone has passed or been removed. For a 24-hour urine collection, the patient is given a large container, which is to be refrigerated between trips to the bathroom. The collection is used to measure urine volume and levels of acidity, calcium, sodium, uric acid, oxalate, citrate, and creatinine – a product of muscle metabolism. The doctor will use this information to

determine the cause of the stone. A second 24-hour urine collection may be needed to determine whether the prescribed treatment is working.

PHARMACOLOGY

MECHANISM OF ACTION :

Potassium Citrate - This medication is used to make the urine less acidic. This effect helps the kidneys get rid of uric acid, thereby helping to prevent gout and kidney stones. This medication can also prevent and treat certain metabolic problems (acidosis) caused by kidney disease. Citric acid and citrate salts (which contain potassium and sodium) belong to a class of drugs known as urinary alkalinizers.

Magnesium Citrate - This medication is a mineral supplement used to prevent and treat low amounts of Magnesium Citrate in the blood. Magnesium Citrate is very important for the normal functioning of cells, nerves, muscles, bones, and the heart. Usually, a well- balanced diet provides normal blood levels of magnesium. However, certain situations cause our body to lose Magnesium Citrate faster than we can replace it from our diet. These situations include treatment with "water pills" (diuretics such as furosemide, hydrochlorothiazide), a poor diet, alcoholism, or other medical conditions (e.g., severe diarrhea / vomiting, stomach /intestinal absorption problems, poorly controlled diabetes).

Potassium citrate and magnesium citrate solution when given orally, the metabolism of absorbed citrate produces an alkaline load.

In addition to raising urinary pH and citrate, this also increases urinary potassium and magnesium. In some patients, potassium citrate causes a transient reduction in urinary calcium.
These changes produce urine that is less conducive to the crystallization of stone-forming salts (calcium oxalate, calcium phosphate and uric acid). Increased citrate in the urine, by complexing with calcium, decreases calcium ion activity and thus the saturation of calcium oxalate. Increased magnesium in the urine, by complexing with oxalate decreases the oxalate ion activity and thus the saturation of calcium oxalate. Citrate and magnesium also inhibits the spontaneous nucleation of calcium oxalate and calcium phosphate.
The increase in urinary pH also decreases calcium ion activity by increasing calcium complexation to dissociated anions. The rise in urinary pH also increases the ionization of uric acid to more soluble urate ion.
Potassium citrate therapy does not alter the urinary saturation of calcium phosphate, since the effect of increased citrate complexation of calcium is opposed by the rise in pH-dependent dissociation of phosphate. Calcium phosphate stones are more stable in alkaline urine.
Pyridoxine is a co-factor of the Alanine-Glyoxylate-Transaminase (AGT) enzyme. Pyridoxine increases the activity of the enzyme AGT, thus glycinate is converted to glycine rather than oxalate, which decreases the urinary oxalate level.

INDICATIONS :

- Prevention of recurrence of calcium oxalate nephrolithiasis and uric acid lithiasis with or without calcium stones.
- Renal tubular acidosis with calcium stones.
- Relief from burning urination.

DOSAGE AND ADMINISTRATION :

Three teaspoons (15ml) of **Alkali – B_6** oral solution diluted with one glass of water, after meals/at bedtime twice daily or as directed by the physician.

CONTRAINDICATIONS :

1.In patients with hyperkalemia (or who have conditions pre-disposing them to hyperkalemia), as a further rise in serum potassium concentration may produce cardiac arrest. Such conditions include: chronic renal failure, uncontrolled diabetes mellitus, acute dehydration, strenuous physical exercise in unconditioned individuals, adrenal insufficiency, extensive tissue breakdown, or the administration of a potassium-sparing agent (such as triamterene, spironolactone or amiloride).

2.In patients in whom there is cause for arrest or delay in passage through the gastrointestinal tract, such as those suffering from delayed gastric emptying, esophageal compression, intestinal obstruction or stricture, or those taking anticholinergic medication.

3.In patients with peptic ulcer disease because of its ulcerogenic potential.

4.In patients with active urinary tract infection.

5.In patients with renal insufficiency (glomerular filtration rate of less than 0.7 ml/kg/min), because of the danger of soft tissue calcification and increased risk for the development of hyperkalemia.

WARNINGS AND PRECAUTIONS :

GENERAL

Hyperkalemia

In patients with impaired mechanisms for excreting potassium, potassium citrate administration can produce hyperkalemia and cardiac arrest. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium citrate in patients with chronic renal failure, or any other condition which impairs potassium excretion such as severe myocardial damage or heart failure, should be avoided. Closely monitor for signs of hyperkalemia with periodic blood tests and ECGs.

Gastrointestinal Lesions

If there is severe vomiting, abdominal pain or gastrointestinal bleeding, Alkali-B6 should be discontinued immediately and the possibility of bowel perforation or obstruction investigated.

Renal Impairment

Potassium citrate is contraindicated in patients with renal insufficiency (glomerular filtration rate of less than 0.7 ml/kg/min), because of the danger of soft tissue calcification and increased risk for the development of hyperkalemia.

Pregnancy

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

Lactation

The normal potassium ion content of human milk is about 13 mEq/l. It is not known if potassium citrate has an effect on this content. Caution should be exercised when potassium citrate is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

DRUG INTERACTIONS :

DiureticsPotassium-sparing:

Concomitant administration of potassium citrate and a potassium sparing diuretic (such as triamterene, spironolactone or amiloride) should be avoided, since the simultaneous administration of these agents can produce severe hyperkalemia.

Drugs that slow gastrointestinal transit time :
These agents (such as anticholinergics) can be expected to increase the gastrointestinal irritation produced by potassium salts.

ADVERS EFFECTS :

Some patients may develop minor gastrointestinal complaints during potassium citrate therapy, such as abdominal discomfort, vomiting, diarrhea, loose bowel movements or nausea. These symptoms are due to the irritation of the gastrointestinal tract, and may be alleviated by taking the dose with meals or snack, or by reducing the dosage. Patients may find intact matrices in feces.
Long-term use of large doses of pyridoxine is associated with the development of severe peripheral neuropathies; the dose at which these occur is controversial.

OVERDOSE :

Treatment of Overdosage:
The administration of potassium salts to persons without predisposing conditions for hyperkalemia causes serious hyperkalemia at recommended dosages. It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic (ECG) changes. Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

- Patients should be closely monitored for arrhythmias and electrolyte changes.
- Elimination of medications containing potassium and of agents with potassium-sparing properties.
- Elimination of foods containing high levels of potassium.
- Intravenous administration of 300-500 ml/hr of 10% dextrose solution containing 10-20 units of crystalline insulin per 1,000 ml.
- Correction of acidosis, if present, with intravenous sodium bicarbonate.
- Hemodialysis or peritoneal dialysis.

PACKAGING INFORMATION :

Alkali - B_6, is available in a bottle of 200 ml**.**