LITHOSTAT® (Acetohydroxamic Acid) is a prescription medicine that is used in patients with chronic urea-splitting urinary infection to prevent the excessive build-up of ammonia in the urine. The usual cause of excess ammonia in your urine is a bacterial infection. Treatment with LITHOSTAT may increase the chance of controlling your infection with antibiotics and may help the treatment of your kidney stones, but will not dissolve them.

Important Safety Information

LITHOSTAT should not be used in place of surgery. Surgical removal of all kidney stones, combined with antibiotics that eliminate the infection causing the stones, will provide the best chance for a cure. LITHOSTAT is not for everyone. You should not take LITHOSTAT if your health and physical condition are a good fit for surgery and/or appropriate antibiotics.

Do not take LITHOSTAT if you are pregnant, may become pregnant, are not using effective contraception, or are breastfeeding. LITHOSTAT contains acetohydroxamic acid (AHA), which has been linked to birth defects in laboratory animals and may cause harm to your unborn child. Some drugs can pass to infants through breast milk, and there may be serious side effects from AHA, so you should stop nursing or discontinue the medicine if you wish to breastfeed.

Do not take LITHOSTAT if you have poor kidney function, if your urinary infection is caused by organisms that do not produce the enzyme urease, or if your infection can be controlled by antibiotics that prevent the specific type of bacteria causing your infection.

Do not take other prescription drugs or over the counter medications while you are taking LITHOSTAT unless you are directed to do so by your doctor. In particular, do not take any medications that contain iron, because LITHOSTAT reacts with iron and both the iron and the LITHOSTAT may become ineffective.

If you have reduced kidney function, your doctor will closely monitor you and may decrease your dosage of LITHOSTAT.

Liver problems have not been reported with LITHOSTAT. However, a substance related to AHA caused significant problems, so your doctor will need to monitor your liver function.

For best results, you must take LITHOSTAT plus antibiotic therapy exactly as prescribed by your physician.

Patients who drank alcohol while taking LITHOSTAT reported a flushing skin reaction which may look like a rash (redness, warmth, and tingling), which lasted approximately 30 minutes. You should not drink alcohol while taking LITHOSTAT.

LITHOSTAT may cause unknown side effects. Some reported side effects include headaches, abdominal discomfort, nausea, vomiting, loss of appetite, general feelings of illness, abnormal breakdown of red blood cells, increase in immature red blood cells, hair loss, shakiness or nervousness, depression, anemia (a reduction in red blood cells), and palpitations.

In early research, life-threatening problems (blood clot in the legs) occurred in several patients with advanced disease. However, in more extensive, later research, these problems have not occurred. No patient has died because of taking LITHOSTAT. The most serious side effects seem to occur in patients with poor kidney function or those with a previous history of these conditions.

Bone marrow depression (a decrease in white blood cells, red blood cells, or platelets) has occurred in laboratory animals receiving large doses of AHA; however, this has not yet been seen in humans. Your doctor will need to monitor your blood while you are on LITHOSTAT.

The cancer-causing potential of long-term use of LITHOSTAT is not known, however, LITHOSTAT alters genetic material and kills tissue cells grown in lab tests. High doses of a chemical related to LITHOSTAT, are associated with liver cancer in laboratory rats. Therefore, LITHOSTAT may have the potential to cause cancer in humans.

Always report any unusual side effects to your doctor immediately. Mild symptoms usually do not require stopping treatment. Severe symptoms may require that you stop treatment temporarily and/or change your dosage.

To report negative side effects, contact Mission Pharmacal Company at 1-800-298-1087 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see XXXXX for full Prescribing Information.