

The logo for Cystistat features the word "cystistat" in a lowercase, sans-serif font. The letter "y" is stylized with a blue-to-white gradient fill. A registered trademark symbol (®) is located at the top right of the "t".**STERILE SODIUM HYALURONATE SOLUTION**

For temporary replacement of the glycosaminoglycan (GAG) layer in the bladder.

DESCRIPTION: The glycosaminoglycan (GAG) layer on the luminal surface of the bladder wall is believed to provide a protective barrier against microorganisms, carcinogens, crystals and other agents present in the urine and has been identified as the primary defense mechanism in protecting the transitional epithelium from urinary irritants.¹ Deficiencies in this GAG layer of the bladder epithelium may destroy its barrier function and allow the adherence of bacteria, microcrystals, proteins and ions, or the movement of ionic and nonionic solute residues (i.e. urea) across the epithelium.² CYSTISTAT® has been developed to temporarily replenish the deficient GAG layer on the bladder epithelium. The active substance is a highly purified sodium salt of hyaluronic acid.

Each CYSTISTAT® vial contains: 40 mg sodium hyaluronate.

DIRECTIONS: Instill the entire volume of this solution into the bladder after any residual urine has been removed. Discard any unused portion. For best results CYSTISTAT® should be retained in the bladder for as long as possible (a minimum of 30 minutes).

There is evidence that the GAG layer of the bladder is deficient in cystitis. This deficiency contributes to the clinical symptoms² in the diseases such as interstitial cystitis,³ cystitis caused by infections, trauma, urolithiasis, urinary retention, neoplasia and radiation induced cystitis.⁴ To alleviate cystitis associated with these conditions, it is recommended that CYSTISTAT® be instilled into the bladder each week for 4-12 treatments and then monthly until symptoms resolve. The attending physician, urologist or radiologist should direct any prophylactic use of CYSTISTAT®.

PRECAUTION: Do not administer to patients with known hypersensitivity reactions. Discontinue use if adverse reactions are experienced. As no clinical evidence is available on the use of Hyaluronic Acid in children, pregnant and lactating women, treatment with CYSTISTAT® is not recommended in these patients.

WARNING: KEEP OUT OF THE REACH OF CHILDREN.

STORAGE: Store at room temperature (15-30°C). Do not freeze.

SUPPLIED: 1 x 50 mL vial of CYSTISTAT® 40 mg.

For single use only. Discard after use.

References:

1. Massing, E.M. Interstitial cystitis and related syndromes, In: Campbell's Urology, 6th edition. Edited by P. C. Walsh, A. B. Retik, T. A. Stamey and E.D. Vaughan, Jr., Philadelphia:W. B. Saunders Co., Vol. 1, Sect VII, Chapter 24, pp 982-1005, 1992.
2. Parsons, C.L., D. Boychuk, S. Jones, R. Hurst and H. Callahan. Glycosaminoglycans: An Epithelial Permeability Barrier. J. Urol. 143: 139-142, 1990.
3. Morales, A., Emerson, L., Nickel, J. C. and Lundie, M: Intravesical hyaluronic acid in the treatment of refractory interstitial cystitis. J. Urol 156: 45-48, 1996.
4. U.S. Patent No's: 5,591,724; 5,880,108; 5,888,986; 6,667,296.
5. European Patent No: 0813417

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