

# cystistat<sup>®</sup>

Get on with life.

## STERILE SODIUM HYALURONATE SOLUTION

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

### DESCRIPTION:

The GAG layer on the internal surface of the bladder wall provides a protective barrier against microorganisms, carcinogens, crystals and other agents present in the urine. It has been identified as the primary defense mechanism from these urinary irritants. Deficiencies in this GAG layer may affect its barrier function and allow the adherence of bacteria, microcrystals, proteins and ions, or the movement of solute residues (i.e. urea). 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 produced by fermentation.

**Each CYSTISTAT vial contains:**  
40mg 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). The GAG layer of the bladder is deficient in cystitis. This deficiency contributes to the clinical symptoms in diseases such as interstitial cystitis, radiation induced cystitis, cystitis caused by infections, trauma, urolithiasis, urinary retention and neoplasia. To alleviate cystitis associated with these conditions, it is recommended that CYSTISTAT be instilled into the bladder each week for four to twelve 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 history of allergy to the components. Discontinue use if adverse reactions are experienced. As no clinical evidence is available on the use of sodium hyaluronate in children, pregnant and lactating women, treatment with CYSTISTAT is not recommended in these patients.

Avoid using CYSTISTAT with instruments sterilized with quaternary ammonium salts solutions.

**WARNING:** KEEP OUT OF REACH OF CHILDREN. DO NOT USE IF PACKAGING IS DAMAGED. TO BE USED BY A PHYSICIAN ONLY.

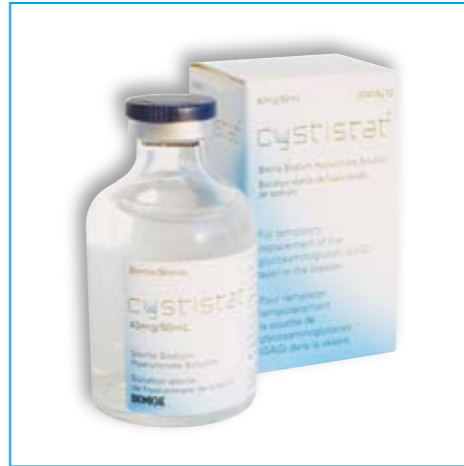
**STORAGE:** Store at room temperature (15-30°). Do not freeze.

**SUPPLIED:** 1 X 50mL vial of CYSTISTAT 40 mg.

Manufactured by: Bioniche Teo., Inverin, Co. Galway, Ireland ©Bioniche Teoranta, Ireland

### CYSTISTAT CLINICAL REFERENCES:

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Get on with life.

Cystistat  
restores the  
urine-tissue  
barrier

Painful Bladder  
Syndrome/  
Interstitial  
Cystitis (PBS/IC)



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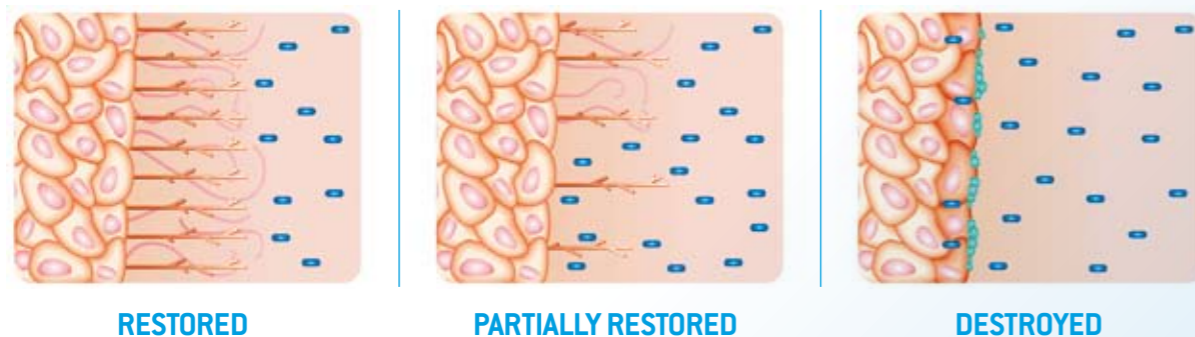
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## A Solution to a Real Problem

Painful Bladder Syndrome / Interstitial Cystitis (PBS/IC) is a debilitating chronic disorder of the bladder. Without adequate therapy it can lead to a state of unremitting Pain and Urinary Frequency, Urgency and Nocturia.

### Restoring the GAG layer



The bladder wall is protected by a thick layer of Proteoglycans and Glycoproteins (Glycosaminoglycans, GAGs). This layer protects the epithelium against toxic agents and bacteria.

**SODIUM HYALURONATE** (Na-HA) is the structural backbone of the extracellular protective layer. Na-HA can help to rebuild the bladder wall structure.

## Cystistat Therapeutic Objectives

REPAIRING  
THE GAG  
DEFICIENCY

RECONSTRUCTING  
THE URINE-TISSUE  
BARRIER

AVOIDING THE  
PASSAGE OF  
POTENTIALLY  
INFLAMMATORY  
SOLUTES

## Cystistat Efficacy

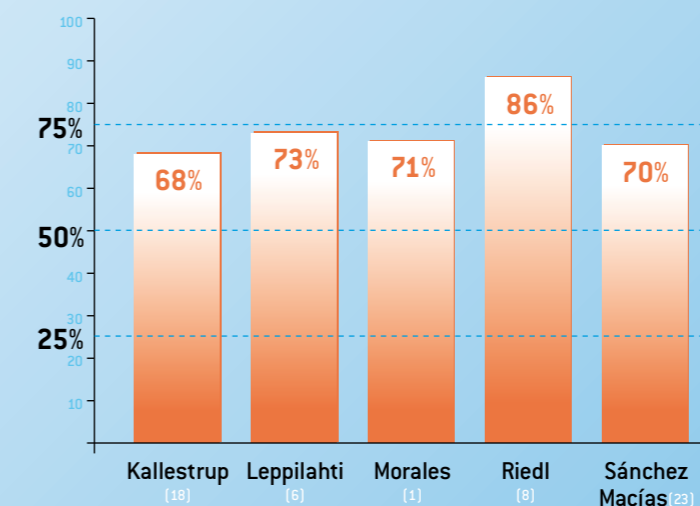
### High efficacy of intravesical Cystistat therapy

“Hyaluronan treatment of interstitial cystitis/painful bladder”  
Ried et al. “Hyaluronan treatment of interstitial cystitis /painful bladder”.  
Int Urogynecol J DOI 10.2007/500192-007-0515-5.  
126 patients with PBS/IC. Average of disease duration 6,1 years

First Cystistat study demonstrating long term efficacy in the treatment of PBS/IC with 65.5% of patients symptom free for up to 5 years

	BEFORE TREATMENT	AFTER CYSTISTAT
VAS SCORE	8,5	3,5
85% SYMPTOMS IMPROVEMENT		84% SIGNIFICANT IMPROVEMENT IN QUALITY OF LIFE

### Several clinical experiences have shown high response rates with Cystistat



- To date, approx. 350.000 instillations of Cystistat have been administered worldwide.
- Close to 50.000 patients have been treated with Cystistat.
- Cystistat is well tolerated as reported in numerous clinical studies involving over 900 patients.