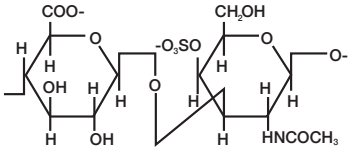
URACYST®

Sterile Sodium Chondroitin Sulfate Solution 2.0%

For replenishment of the glycosaminoglycan (GAG) layer in the urinary bladder

Description: Chondroitin Sulfate is an acidic mucopolysaccharide and is one of the glycosaminoglycans (GAGs). Its repeating disaccharide unit is made of a glucuronic acid and a galactosamine with one sulfate group in ß (1-3') linkage.



Glucuronic acid N-acetyl galactosamine sulfate

This disaccharide unit is polymerized ß (1-4') linkage. The O-sulfation at C-4 is Chondroitin Sulfate A. O-sulfation at C-6 is Chondroitin Sulfate C.

The luminal surface of the bladder is coated with a layer of glycosaminoglycans (GAGs) that provide a protective, impermeable barrier to the bladder. The highly charged poly anionic molecules of GAGs bind with water molecules; thereby creating a molecular layer of water between the surface to which GAGs are bound and urine. This layer inhibits adherence of bacteria, microcrystals, carcinogens, and ions. Damage to this GAG layer may result in defects to its protective barrier function, allowing irritation to the bladder wall.

Chondroitin Sulfate is an important component of the bladder GAGs and its instillation into the bladder can replenish the deficient GAG layer on the bladder epithelium.

Blister Pack Directions: To be opened immediately prior to use. To access vial, grip tab at top while supporting neighbouring strip and peel off one strip as needed. To separate individual blister packs, fold on perforation and bend back and forth several times prior to tearing.

Administration:

For active treatment: Uracyst® should be used full strength by instillation into the bladder after residual urine has been removed.

Uracyst® is provided for patients with GAG damage ranging from mild to severe, where a physician feels benefit would be derived from a GAG replenishment therapy with Chondroitin Sulfate.

Repeat the instillation of Uracyst® weekly for four weeks, then monthly thereafter until symptoms are relieved. Some patients benefit from up to 6 weekly instillations, then monthly thereafter depending on their symptomatic response.

Uracyst® contains 20.0 mg/mL of Sodium Chondroitin Sulfate. Uracyst® contains neither preservative nor anti-microbial, therefore any unused portion must be discarded. For optimum results, Uracyst® should be retained in the bladder as long as possible (not less than 30 minutes).

Precaution: Do not administer to patients with known hypersensitivity reactions.

Storage: Store 2° to 25°C. **DO NOT FREEZE.** Bring the contents to the room temperature before use.

Supplied: Each mL contains 20.0 mg Sodium Chondroitin Sulfate.

4 x 20 mL in single dose glass vials. Discard unused portions. Only the contents of the vial are sterile.

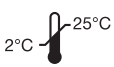
Batch Number


For single use only


Use by


Refer to instruction leaflet


Manufacturer



Store at 2 - 25° C

Sterile by aseptic processing and sterile filtration


Do not use if package is damaged

Catalogue Number

® registered trade mark
Uracyst® Canadian Pat # 2269260
USA Patent # 6083933, 7772210
Australia Patent # 2004212650
China Patent # 1758920
International patents pending

301-47 Rev 2
Date of Revision: 2019-02

Aralez Pharmaceuticals

Aralez Pharmaceuticals Canada Inc.,
7100 West Credit Avenue,
Mississauga, ON, Canada
L5N 0E4
Phone: 1-866-391-4503
www.aralez.com