50105421

西施泰®

无菌透明质酸钠液说明书

【产品名称】 无菌透明质酸钠液
【型号规格】 40mg/50ml
【医疗器械注册证编号】 国械注进 20193142039
【产品技术要求编号】 国械注进 20193142039
【产品性能结构及组成】 该产品由透明质酸钠、氯化钠、磷酸二氢钠二水合物、磷酸氢二钠十二水合物、注射用水组成。每瓶 50ml，其中透明质酸钠的含量为 40mg。以无菌状态供货，一次性使用。
【产品适用范围】 该产品用于膀胱上皮氨基葡萄糖保护层缺乏的临时替代。

【说明】

氨基葡萄糖（GAG）层位于膀胱壁的内表层，被认为是防御尿中微生物、致癌物、微晶体和其他药物的保护屏障，已被看作是移行上皮抵抗尿中刺激物的主要防护机制。GAG 层的缺损可能会影响其屏障功能而导致细菌、微晶体、蛋白和离子的粘附或离子型及非离子型溶质残渣（如尿素）的迁移。本品可以临时对膀胱上皮细胞的 GAG 层缺损进行修补。其活性成份为透明质酸钠盐。

【禁忌症】 尚不明确。

【注意事项】

1、对本品成份有过敏史者请勿使用。
2、如出现不良反应请停止使用。
3、由于没有透明质酸钠用于儿童、孕妇和哺乳妇女的临床证据，所以不推荐此类患者使用本品。
4、避免与季铵盐溶液消毒过的器械同时使用。

【警告】

1、请置于儿童不可触及处。
2、如果包装破损，请勿使用。
3、本品灭菌方式为无菌过滤，仅供一次性使用，用后请弃置。

【安装和使用说明】

尿液排空后将本溶液全部缓慢注入膀胱内，弃置未用部分。为达到最佳疗效，尽可能长时间地将本品保留在膀胱内（至少 30 分钟）。

膀胱炎时 GAG 层受损，缺损可导致以下疾病出现其相应的临床症状，如间质性膀胱炎，感染、创伤、尿石症、尿潴留及肿瘤导致的膀胱炎，放射导致的膀胱炎等。为缓解以上病因导致的膀胱炎，推荐每周使用 1 次本品进行膀胱灌注，4~12 周治疗后，每月进行 1 次治疗直至症状缓解。治疗医生（泌尿科医师或放射科医师）应指导本品所有预防性使用。

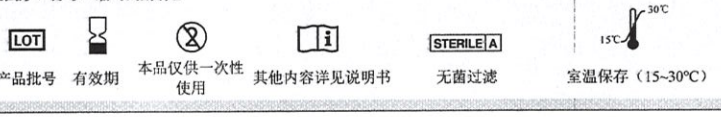
【包装】 每盒装 1 瓶 40mg/50ml 无菌透明质酸钠液。
【产品维护和保养方法】 无特别说明。
【储存条件】 室温保存（15~30℃），请勿冷冻。
【运输条件、方法】 运输应防止重压、阳光直晒和雨雪浸淋，不得冷冻。
【生产日期】 见小盒。
【有效期限】 36 个月
【配件清单】 不适用。
【说明书修订日期】 2026年05月09日
【注册人】及【生产企业】

名　　称：Mylan Institutional（爱尔兰迈蓝公司）
住　　所：Coill Rua, Inverin, County Galway, Republic of Ireland
生产地址：Coill Rua, Inverin, County Galway, Republic of Ireland
电话号码：+353 91 505600　　传真号码：+353 91 593228
网　　址：www.cystistat.com

【代理人】及【售后服务机构】

名　　称：天津康哲医药科技发展有限公司
住　　所：天津经济技术开发区南港工业区综合服务区办公楼 D 座二层 216-217 室
电话号码：022-59005099

【图形、符号、缩写的解释】



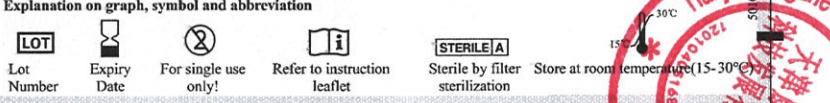
产品批号　有效期　本品仅供一次性使用　其他内容详见说明书　无菌过滤　室温保存（15~30℃）

50105421

cystistat®

Instructions of Sterile Hyaluronate Solution

Name of Device: Sterile Hyaluronate Solution
Model: 40mg/50ml
Registration No.: NMPA(I)20193142039
Product technology requirement No.: NMPA(I)20193142039
Performance, Structure and Composition: The product is composed of hyaluronic acid sodium salt, sodium chloride, sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, water for injection. Each product vial is 50ml, containing 40 mg hyaluronic acid sodium salt. The product is supplied under sterile state, and for single use only.
Indications: For temporary replacement of the glycosaminoglycan (GAG) layer in the bladder.
Descriptions: 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. 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. The product has been developed to temporarily replenish the deficient GAG layer on the bladder epithelium. The active substance is a sodium salt of hyaluronic acid.
Contraindication:
Unknown.
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 the product is not recommended in these patients.
Avoid using the product with instruments sterilised with quaternary ammonium salts solutions.
Warning:
KEEP OUT OF THE REACH OF CHILDREN.
DO NOT USE IF PACKAGING IS DAMAGED.
STERILE BY FILTER STERILIZATION. FOR SINGLE USE ONLY. DISCARD AFTER USE.
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, the product 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 symptoms in the diseases such as interstitial cystitis, cystitis caused by infections, trauma, urolithiasis, urinary retention, neoplasia and radiation induced cystitis. To alleviate cystitis associated with these conditions, it is recommended that the product 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 the product.
Package: 1 × 50mLvial of Sterile Hyaluronate Solution 40 mg.
Product maintenance method: No special suggestion is available.
Storage: Store at room temperature (15~30℃). Do not freeze.
Condition and methods of transportation: Avoiding great pressure, direct contact with sun, rain and snow, and freeze during transportation.
Date of Manufacture: See the carton
Shelf Life: 36 months
List of accessories: Not applicable.
Date of Revision: 09 May 2026
Registrant/ Manufacturer
Name: Mylan Institutional
Add: Coill Rua, Inverin, County Galway, Republic of Ireland
Tel:+ 353 91 505600
Fax:+ 353 91 593228
Web Site:www.cystistat.com
Representatives/Service Agent
Name: Tianjin Kangzhe Pharmaceutical Technology Development Co., Ltd.
Add: Room 216-217, 2/F, Building D, Comprehensive Service Area,
Nangang Industrial Zone,Tianjin Economic-Technological Development Area
Tel: 022-59005099
Explanation on graph, symbol and abbreviation



Lot Number　Expiry Date　For single use only!　Refer to instruction leaflet　Sterile by filter sterilization　Store at room temperature(15-30℃)

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Smurfit Westrock

Pre-Press for Leaflets
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Client: Mylan Teoranta
Client Code: 1523
Job Order: 50105421
Job/Item Number: 280148
Proof Version: K
Product Description: Cystistat Insert

Flat Size	354 × 266 mm
Pages	1 pp
Drawing	2019_0181
Repro/Pharmacode	n/a

Colours (Front or Back): Black
Options (Front or Back):
Technical Information (Front or Back): Trim Area, Cutter
Contact Details:

Artworker	Matthew Holness
Date Received	14/05/2026 09:51:01
CS Contact	
Customer Contact	Aine O'Malley

Customer Approval

Approved by:　Approval Date:
Signature:

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