ADSTILADRIN®
(nadofaragene firadenovec-vncg)
suspension, for intravesical use / 3×10^{11} viral particles/mL

Product Acquisition Overview

- **APPROVED** for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors[1]

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information at www.FerringUSA.com/PI/ADSTILADRIN.

Product acquisition overview

ADSTILADRIN® is an intravesical instillation given once every 3 months to patients in a urology office. A dose of 75 mL is administered through a urinary catheter and should be left in the bladder for 1 hour following instillation[1]

Product information[1]	
Name	ADSTILADRIN
Generic name	nadofaragene firadenovec-vncg
Package presentation	Carton of four 20 mL vials (1 dose)
Wholesale Acquisition Cost[2]	$60,000 per dose
Dosage form	Sterile, clear to opalescent suspension single-use vials
National Drug Code (NDC)	Carton, 4-vial package: **NDC** 55566-1050-01
Specialty distributors*	• Besse Medical (1-800-252-8759) • Optum Frontier Therapies (1-833-754-6457)
Specialty pharmacy	Optum Frontier Therapies (1-855-768-9727)

*It is recommended that provider sites and offices establish accounts with specialty distributors, Besse Medical and Optum Frontier Therapies, to ensure access to ADSTILADRIN.

Availability

ADSTILADRIN will be supplied via an **early experience program for clinical trial sites and select urology clinics**. Ferring is scaling up manufacturing with the ambition of meeting the needs of as many patients as possible. As manufacturing increases, **ADSTILADRIN will be available to clinics and appropriate NMIBC patients who need it**

Storage requirements[1]

ADSTILADRIN has specific storage and handling requirements to preserve the quality of the viral particles

Upon receipt, cartons of ADSTILADRIN can be stored as indicated below:

- In a freezer ≤-60°C (≤-76°F) until expiry date printed on the carton
- In a freezer between -25°C to -15°C (-13°F to 5°F) up to 3 months, without exceeding the original expiry date printed on the vial and outer carton
  - When stored in freezer, the date of placement in freezer should be noted

Ordering timeline and day of delivery expectations

For order to be received at site of care by†	Order must be placed at SD within timeframe‡	Order will be fulfilled by ICS and expected to ship by
10:30 AM Tuesday	Thursday 2 PM – Monday 2 PM	Monday
10:30 AM Wednesday	Monday 2 PM – Tuesday 2 PM	Tuesday
10:30 AM Thursday	Tuesday 2 PM – Wednesday 2 PM	Wednesday

DAY OF DELIVERY Expect to receive a call from **AeroSafe (585-760-2830)** in which they will provide:
- Storage instructions
- Shipper return instructions

ICS=[TBD]; SD=specialty distributor.

†Shipment receipt times listed as local times at the site of care, if available in that geography.
‡Order placement times are listed in Central Standard Time to account for Ferring distribution center customer service.

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Coding

ICD-10-CM codes[2]	
C67.0–C67.9	Malignant neoplasm of bladder
D09.0	Carcinoma in situ of bladder
Z85.51	Personal histpry of malignant neoplasm of bladder

HCPCS code[3]	
J9029	Instillation, nadofaragene firadenovec-vncg, per therapeutic dose

CPT code[4]	
51720	Bladder instillation of anti-carcinogenic agent (including retention time) (catheterization is not separately billable for bladder instillation of ADSTILADRIN)

Indication and Important Safety Information

INDICATION

ADSTILADRIN is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: ADSTILADRIN is contraindicated in patients with prior hypersensitivity reactions to interferon alfa or to any component of the product.

WARNINGS AND PRECAUTIONS

- ***Risk with delayed cystectomy:*** Delaying cystectomy in patients with BCG-unresponsive CIS could lead to development of muscle invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after 3 months or if CIS recurs, consider cystectomy.
- ***Risk of disseminated adenovirus infection:*** Persons who are immunocompromised or immunodeficient may be at risk for disseminated infection from ADSTILADRIN due to low levels of replication-competent adenovirus. Avoid ADSTILADRIN exposure to immunocompromised or immunodeficient individuals.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

Indication and Important Safety Information (cont'd)

DOSAGE AND ADMINISTRATION: Administer ADSTILADRIN by intravesical instillation only. ADSTILADRIN is not for intravenous use, topical use, or oral administration.

USE IN SPECIFIC POPULATIONS: Advise females of reproductive potential to use effective contraception during ADSTILADRIN treatment and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during ADSTILADRIN treatment and for 3 months after the last dose.

ADVERSE REACTIONS: The most common (>10%) adverse reactions, including laboratory abnormalities (>15%), were glucose increased, instillation site discharge, triglycerides increased, fatigue, bladder spasm, micturition (urination urgency), creatinine increased, hematuria (blood in urine), phosphate decreased, chills, pyrexia (fever), and dysuria (painful urination).

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch or call 1-800-332-1088. You may also contact Ferring Pharmaceuticals at 1-888-FERRING.

Please see full Prescribing Information at www.FerringUSA.com/PI/ADSTILADRIN.

References: 1. ADSTILADRIN [package insert]. Kastrup, Denmark: Ferring Pharmaceuticals; December 2022. **2.** Data on file. ADSTILADRIN CSR, Ferring Inc. Parsippany, NJ. **3.** Centers for Medicare & Medicaid Services. 2023 alpha numeric HCPCS file. Accessed July 5, 2023. https://www.cms.gov/medicare/coding/medhcpcsgeninfo/prior-years-cms-hcpcs-levelii-coding-decisions-narrative-summary **4.** American Medical Association (AMA). CPT® 2023 Professional Edition. Chicago, IL: AMA; 2019.

FERRING PHARMACEUTICALS

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