

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



GETTING STARTED WITH ADSTILADRIN

FOR PATIENTS

**THE FIRST AND ONLY FDA-approved gene therapy delivered directly
in the bladder for non-muscle-invasive bladder cancer**

For when Bacillus Calmette-Guérin (BCG) treatment does not work,
and you are unable to or have decided not to
have your bladder removed.

INDICATION:

ADSTILADRIN is a treatment for adults who have all the following:

- High-risk non-muscle-invasive bladder cancer
- Cancer that is no longer responding to Bacillus Calmette-Guérin (BCG) therapy
- Cancer that started in the bladder and has not spread (this is called carcinoma in situ or CIS)
- Cancer with or without slender, finger-like tumor growths (papillary tumors) growing into the bladder space, away from the bladder wall

**Please see Important Safety Information throughout and
full Prescribing Information for ADSTILADRIN.**

Living with non-muscle-invasive bladder cancer (NMIBC)

The bladder is a part of our body where urine is stored. NMIBC is bladder cancer that has not spread past the lining of the bladder into the muscle. **It is the most common type of bladder cancer.**



About **3 out of 4** people with bladder cancer have NMIBC.

For early-stage bladder cancer, BCG is a common first therapy. **But sometimes, BCG therapy can stop working.** When you find that you need additional treatment for bladder cancer, you may be concerned about what comes next.

If BCG therapy stops working, there are only a few approved treatment options available to try before you may need to have your bladder removed. But there are reasons to feel hopeful—and treatments that may help you keep your bladder.



Learn how ADSTILADRIN (*ad-still-uh-drin*), a first-of-its-kind gene therapy for NMIBC, can help.

IMPORTANT SAFETY INFORMATION

Who should not receive ADSTILADRIN?

Do not receive ADSTILADRIN if you have a sensitivity to interferon alfa or any of its components.

Please see Important Safety Information throughout and full Prescribing Information for ADSTILADRIN.

What is ADSTILADRIN?

It is important to learn all you can about treatment, including how it works, how it was studied, and what to expect before, during, and after treatment.

Here are a few quick facts about ADSTILADRIN to help you get started.

WHAT ADSTILADRIN IS	WHAT ADSTILADRIN IS NOT
 ADSTILADRIN is a gene therapy.	 ADSTILADRIN is NOT chemotherapy.
 ADSTILADRIN delivers the gene that encodes for the interferon alfa-2b protein to your bladder so it can fight the cancer.	 ADSTILADRIN does not change your genes like some other gene therapies.
 ADSTILADRIN is a targeted treatment. It works with your body's immune cells.	 ADSTILADRIN ONLY fights the cancer in your bladder. It DOES NOT impact your overall immune system. This may help reduce side effects.
 ADSTILADRIN is a treatment that allows you to stay in the care of your urologist.	 ADSTILADRIN does not require you to change providers for treatment.

Your healthcare team will talk to you about your options. Work closely with them to create a treatment plan that is made just for you.

Treatment with ADSTILADRIN



ADSTILADRIN is delivered directly into the bladder by your urologist every 3 months.



ADSTILADRIN is delivered using a catheter that goes directly into your bladder. This is like the process for BCG treatment. The posttreatment directions are like those for after BCG treatment as well. **Learn more about the steps you need to take on [page 4](#).**



ADSTILADRIN is given by your urologist in their office.

Your urologist will also manage your care after treatment, so your healthcare team will conveniently remain the same.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of ADSTILADRIN?

The most common side effects of ADSTILADRIN include:

Urinary discharge, fatigue, bladder spasm, urgency to urinate, and blood in your urine.

These are not all the possible side effects of ADSTILADRIN. Call your doctor for medical advice about side effects. 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 Important Safety Information throughout and full [Prescribing Information](#) for ADSTILADRIN.

ADSTILADRIN was shown to be well tolerated and effective

ADSTILADRIN was studied in 98 people with high-risk NMIBC whose cancer did not respond to BCG therapy.

WELL TOLERATED

- **Most side effects were mild and manageable** and went away after 2 days
 - 11% of people taking ADSTILADRIN had serious side effects
- 3 people had to stop ADSTILADRIN due to side effects
- There were **no deaths** due to treatment-related side effects with ADSTILADRIN
 - 34% of people paused treatment due to side effects but then continued treatment

EFFECTIVE

AT 3 MONTHS



- **More than half of the people** who took ADSTILADRIN had a **complete response** (no signs of bladder cancer) after the first dose
 - Of this group, almost half (46%) **stayed bladder cancer free** for a year or longer

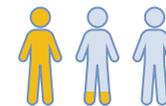
AT 1 YEAR



Most people treated with ADSTILADRIN did not need to have their bladder removed (a procedure called cystectomy)

Almost everyone (95%) given ADSTILADRIN **did not have their cancer spread** outside of the bladder

AT 2 YEARS



- **More than 1 in 3** people (36%) who had a complete response at 3 months were **still bladder cancer free***

***This was part of a separate analysis that was done at a later time. Talk to your doctor about the limitations of these 2-year data.**

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What to expect when taking ADSTILADRIN

Work closely with your healthcare provider before, during, and after your treatment to ensure a successful visit.



BEFORE YOUR TREATMENT

Be sure to let your healthcare provider know:

- If you have an allergy to any ingredient in ADSTILADRIN
- **All the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements
- If you are **pregnant or plan on becoming pregnant**
- If you have any **symptoms of a urinary tract infection** such as:
 - Painful or burning sensation when you urinate
 - Urgent or frequent trips to the restroom
 - Pain or pressure in lower abdominal or pelvic area
- If you cannot make your appointment
 - **Be sure to alert them as early as possible and schedule another appointment at a time that works for you**



DURING YOUR TREATMENT

You should:

- **Wear comfortable clothes**—the treatment will last for at least 1 hour
- **Avoid using the restroom** until your treatment is done
- Your doctor may have you **change position every 15 minutes**
- Let your healthcare provider know if you have any **cramping** or feel like you **urgently need to urinate**

IMPORTANT SAFETY INFORMATION

What should I tell my healthcare provider?

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see **Important Safety Information throughout and full Prescribing Information for ADSTILADRIN.**



AFTER YOUR TREATMENT

Make sure you:

- Have **bleach ready at home**
 - Add about half a cup of bleach to the toilet bowl before you urinate
 - After urinating, wait 15 minutes before flushing the toilet
 - Repeat these steps every time you urinate for the first 2 days after treatment
- **Schedule your next appointment**, which will be in 3 months



Remember to stay in regular contact with your healthcare team. They can answer any questions you may have about the ADSTILADRIN treatment process.

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What to expect after ADSTILADRIN treatment

Important things to know after receiving your first dose:

Some side effects may occur after taking ADSTILADRIN. The most common side effects of ADSTILADRIN include:



- Urinary discharge
- Fatigue
- Bladder spasm
- Urgency to urinate
- Blood in your urine

These are not all the possible side effects of ADSTILADRIN. Call your doctor for medical advice about side effects if they continue for more than 2 days after treatment. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to **Ferring Pharmaceuticals at 1-888-337-7464, option 1.**



Other important things to consider:

- Your healthcare team may suggest keeping movement to a minimum
 - Ask your team if they suggest any movement restrictions after you have received treatment
- After your first dose, your doctor may monitor how well ADSTILADRIN is working
 - They will do this with a procedure that uses a thin, tubelike instrument with a light that allows the doctor to view the inside of your bladder

Please see **Important Safety Information** throughout and full **Prescribing Information** for ADSTILADRIN.

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Ferring is here to help support you during your treatment

Ferring Access Support is a program that offers patient assistance, coverage support, and other valuable resources.

How it works:

- 1 Your healthcare provider will help you enroll in Ferring Access Support.
- 2 After that, a **Ferring Access Support case manager will contact you** to help you learn more about what to expect during the process.
- 3 They may also reach out if there is any missing information in your profile or to remind you of an upcoming appointment.

Services offered:

Benefits investigation support

Financial assistance for patients

Dedicated reimbursement support

Your case manager is here to help

It's important to work closely with your case manager to avoid delays in your treatment. They may call from a phone number that you don't recognize, so try your best to answer those calls.



Ferring Access Support

1-844-623-6669

Monday to Friday, 9 AM to 6 PM eastern time

Your case manager will work with your health insurer to determine whether ADSTILADRIN is covered by your plan. They can also share information about other programs, such as the ADSTILADRIN Copay Program or Ferring Access Support Patient Assistance Program, to help you get access to ADSTILADRIN. Terms and conditions apply.

Contact your Ferring Access Support case manager right away if you have any change in insurance coverage.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ADSTILADRIN?

Individuals who are immunosuppressed or immune-deficient should not prepare, administer, receive or come into contact with ADSTILADRIN.

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Shown to help you stay bladder cancer free



EFFECTIVE

- **More than half of the people** who took ADSTILADRIN in a clinical trial **had a complete response** (no signs of bladder cancer) after the first dose at 3 months
 - Most people (74%) treated with ADSTILADRIN did not need to have their bladder removed at 1 year
- **More than 1 in 3 people** who had a complete response at 3 months were still **bladder cancer free at 2 years***

*This was part of a separate analysis that was done at a later time. Talk to your doctor about the limitations of these 2-year data.



WELL TOLERATED

- **Most side effects were mild and manageable** and went away after 2 days
 - 11% of people taking ADSTILADRIN had serious side effects
- 3 people had to stop ADSTILADRIN due to side effects



CONVENIENT DOSING SCHEDULE

- Delivered **once every 3 months** into the bladder through a urinary catheter
- **Given and managed by your urologist in their office**

For additional information, go to www.adstiladrin.com
or call 1-888-337-7464. Once you call, select option 1.

IMPORTANT SAFETY INFORMATION

What other information should I know about using ADSTILADRIN?

For 2 days following treatment, voided urine should be disinfected for 15 minutes with an equal volume of bleach before flushing.

For more important information, go to www.adstiladrin.com or call 1-888-337-7464.

Please see Important Safety Information throughout and full Prescribing Information for ADSTILADRIN.

