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Adstiladrin (*nadofaragene firadenovec*)

A plain-language overview of Adstiladrin and why it is authorised in the EU

What is Adstiladrin and what is it used for?

Adstiladrin is a gene therapy medicine used to treat adults with non-muscle invasive bladder cancer (NMIBC), a type of cancer that affects the lining of the bladder. It is intended for people with cancer that has not spread beyond the inner lining of the bladder (known as carcinoma in situ).

Adstiladrin is used when the cancer has not responded to treatment with Bacillus Calmette-Guérin (BCG), a standard bladder cancer treatment that stimulates the immune system (the body's natural defences).

The medicine contains the active substance nadofaragene firadenovec.

How is Adstiladrin used?

Adstiladrin can only be obtained with a prescription. Treatment should be supervised by a doctor experienced in the management of patients with NMIBC. It is given once every three months as a liquid directly into the bladder through a tube into the urethra (the tube through which urine leaves the body).

The duration of treatment depends on how well it works and how well the patient tolerates it. The doctor may have to stop treatment if the disease comes back or if side effects become too severe.

Before each treatment, patients are usually given one dose of another medicine to prevent problems such as bladder irritation.

For more information about using Adstiladrin, see the package leaflet or contact your healthcare provider.

How does Adstiladrin work?

Adstiladrin is a type of gene therapy that uses a modified virus to deliver a gene into the cells. The gene used in Adstiladrin is responsible for making a protein called interferon alfa-2b.
The virus used has been changed so that it cannot multiply or cause infection.

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When Adstiladrin is placed into the bladder, the virus enters the cells lining the bladder, including cancer cells. These cells are then able to make interferon alfa-2b, which slows down or stops the cancer cells from growing and also helps to stimulate the immune system to attack them.

What benefits of Adstiladrin have been shown in studies?

The benefits of Adstiladrin were evaluated in one main study involving 103 adults with BCG-unresponsive NMIBC with carcinoma in situ (with or without papillary tumours). All patients received at least one dose of Adstiladrin, given into the bladder. The study did not compare Adstiladrin with another treatment or placebo (a dummy treatment). Three months after starting treatment with Adstiladrin, 53% of patients had a complete response, meaning that they had no detectable signs of cancer. This response lasted for about 10 months on average.

Studies carried out with Adstiladrin are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Adstiladrin?

For the full list of side effects and restrictions with Adstiladrin, see the package leaflet.

The most common side effects with Adstiladrin (which may affect more than 1 in 10 people) include urinary tract infection (infection of the parts of the body that collect and pass out urine) and symptoms linked to the way the medicine is used. These include discharge of fluid at the site where the medicine is instilled, bladder spasm (sudden tightening of the bladder that can cause pain or urgent need to urinate), micturition urgency (sudden urge to pass urine), haematuria (blood in the urine), dysuria (painful urination), lower urinary tract pain, and pollakiuria (abnormally frequent urination). In addition, other common side effects (which may also affect more than 1 in 10 people) include tiredness, fever, chills, headache, and diarrhoea.

Some side effects can be serious. The most frequent (which may affect more than 1 in 10 people) include syncope (fainting).

Why is Adstiladrin authorised in the EU?

At the time of authorisation, there were only limited treatments for NMIBC that did not respond to BCG. The main treatment option was surgery to remove the bladder, which is not suitable for all patients. Adstiladrin offers a new treatment option for patients who are unwilling or unfit for surgery.

Results from a small, short-term, non-comparative study suggest that Adstiladrin can benefit these patients, although the duration of the benefits was limited. The safety of the medicine was considered acceptable considering the seriousness of NMIBC and given the lack of alternative treatments at the time of authorisation. However, there is a potential risk of the disease spreading into the bladder muscle (muscle-invasive) or other parts of the body (metastatic) when surgery is delayed, which should be taken into account when using the medicine.

Adstiladrin has been given conditional authorisation for use in the EU. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Adstiladrin. It must submit results from an ongoing study on the effectiveness and safety of the medicine in adults with NMIBC. Every year, the Agency will review any new information that becomes available.

What measures are being taken to ensure the safe and effective use of Adstiladrin?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Adstiladrin have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Adstiladrin are continuously monitored. Suspected side effects reported with Adstiladrin are carefully evaluated and any necessary action taken to protect patients.

Other information about Adstiladrin

Adstiladrin received a conditional marketing authorisation valid throughout the EU on 28 May 2026.

Further information on Adstiladrin, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/adstiladrin.

For information about the availability of this medicine in your country, contact your national competent authority.

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