26 March 2026
EMA/CHMP/66758/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Adstiladrin

nadofaragene firadenovec

On 26 March 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Adstiladrin. As Adstiladrin is an advanced therapy medicinal product, the CHMP positive opinion is based on an assessment by the Committee for Advanced Therapies.

The applicant for this medicinal product is Ferring Pharmaceuticals A/S.

The full indication is:

> Adstiladrin is indicated as monotherapy for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.

Adstiladrin will be available as a 3 x 10^{11} viral particles/ml intravesical suspension. The active substance of Adstiladrin is nadofaragene firadenovec, an antineoplastic cell and gene therapy (ATC code: L01XL10). Nadofaragene firadenovec is a non-replicating, recombinant type 5 adenovirus vector-based gene therapy containing the human IFNα2b transgene. Its intravesical administration results in the entry of viral particles into the tumour cells and the urothelium of the bladder, leading to the expression of the IFNα2b protein in such cells, which in turn activates an anti-tumour immune response.

The benefits of Adstiladrin are a 53.4% (95% CI: 43.3, 63.3) complete response rate with a median duration of response of 9.7 months in the target population (n=103) in a single-arm, open-label, multicentre pivotal study. The most common side effects with Adstiladrin are instillation site discharge, bladder spasm, micturition urgency, haematuria, dysuria, urinary tract infection, lower urinary tract pain, pollakiuria, fatigue, pyrexia, chills, headache and diarrhoea.

Treatment with Adstiladrin should be initiated and administered in clinical centres and supervised by a physician experienced in the management of patients with NMIBC.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.