



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Anktiva (*nogapendekin alfa inbakicept*)

An overview of Anktiva and why it is authorised in the EU

### What is Anktiva and what is it used for?

Anktiva is a 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).

Anktiva is used with Bacillus Calmette-Guérin (BCG), a standard bladder cancer treatment that stimulates the immune system, when the cancer has not responded to treatment with BCG alone.

The medicine contains the active substance nogapendekin alfa inbakicept.

### How is Anktiva used?

Anktiva can only be obtained with a prescription. It is given as a liquid together with BCG directly into the bladder through the urethra, the tube through which urine leaves the body.

Treatment starts with an induction phase during which Anktiva is given once a week for 6 weeks. If the cancer persists 3 months after start of treatment, the induction phase may be repeated.

People with no signs of cancer after induction continue with Anktiva as maintenance therapy, given once a week for three weeks at months 4, 7, 10, 13, and 19. People with papillary tumours (growths that start in the bladder lining and form finger-like shapes extending into the bladder cavity) after induction should have these tumours removed by surgery before starting maintenance treatment.

Doctors will carry out regular tests to monitor the disease in their patients. People who have no signs of cancer after around two years of induction and maintenance treatment may receive a further 9 doses of Anktiva, given over an additional year.

For more information about using Anktiva, see the package leaflet or contact your doctor or pharmacist.

### How does Anktiva work?

The active substance of Anktiva, nogapendekin alfa inbakicept, is a type of protein that attaches to receptors (targets) on certain immune cells, called interleukin-15 receptors. This activates these cells to target and destroy cancer cells.

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## **What benefits of Anktiva have been shown in studies?**

Anktiva was investigated in one main study involving 100 adults with BCG-unresponsive NMIBC. All patients received Anktiva in combination with BCG, given into the bladder once a week for 6 weeks. The study did not compare Anktiva with another treatment or placebo (a dummy treatment). Three months after start of treatment with Anktiva and BCG, signs of cancer had disappeared in 71% of patients, and this response lasted for about 27 months on average.

## **What are the risks associated with Anktiva?**

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

The most common side effects with Anktiva (which may affect more than 1 in 10 people) include dysuria (painful urination), haematuria (blood in the urine), pollakiuria (abnormally frequent urination), urinary tract infection (infection of structures that carry urine), micturition urgency (sudden, strong need to urinate), tiredness, chills, muscle and bone pain and fever.

Some side effects can be serious. The most frequent (which may affect up to 1 in 10 people) include urinary tract infection, bacteraemia (bacteria in the blood) and haematuria.

## **Why is Anktiva authorised in the EU?**

At the time of authorisation, there were no authorised 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. Anktiva offers a new treatment option for patients who are unwilling or unfit for surgery. The medicine delays the worsening of the disease in patients who cannot undergo surgery and addresses an important unmet need.

Results from the main, small, short-term study suggest that Anktiva given with BCG can benefit these patients. 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, healthcare professionals should carefully consider the potential risk of the disease spreading into the bladder muscle (muscle-invasive) or other parts of the body (metastatic) when surgery is delayed.

Anktiva has been given conditional authorisation. 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 Anktiva. It must submit the long-term results of the ongoing main study as well as data from another study comparing Anktiva and BCG with BCG alone in patients who have not received BCG before. 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 Anktiva?**

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

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

## **Other information about Anktiva**

Anktiva received a conditional marketing authorisation valid throughout the EU on 16 February 2026.

Further information on Anktiva can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/anktiva](https://ema.europa.eu/medicines/human/EPAR/anktiva).

This overview was last updated in 02.2026.