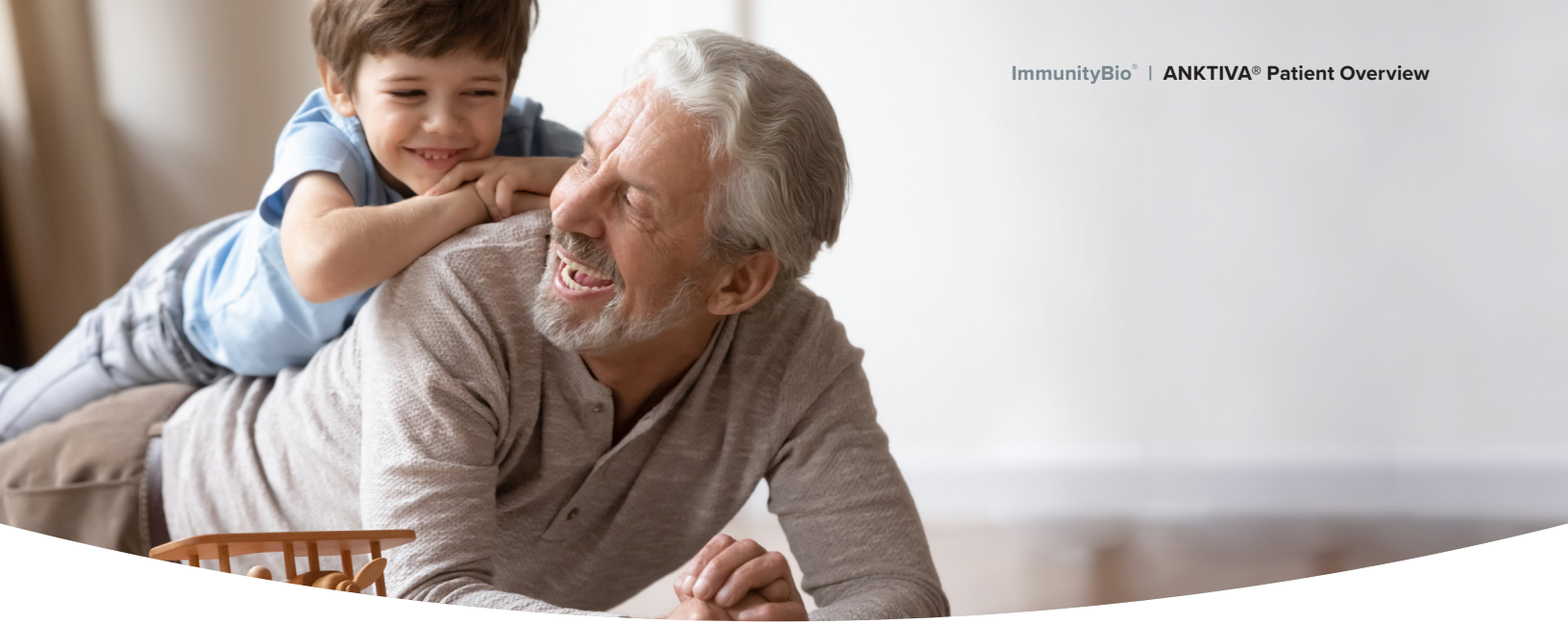
Anktiva®
(nogapendekin alfa inbakicept-pmln)

Getting Started with ANKTIVA®

For Patients

IMPORTANT SAFETY INFORMATION

Please see Important Safety Information throughout and full Prescribing Information for ANKTIVA



What is ANKTIVA®?

ANKTIVA is the first U.S. FDA-approved immunotherapy that activates a type of cell called a natural killer (NK) cell, part of the body's natural immune system, to attack and kill non-muscle invasive bladder cancer (NMIBC) cells.[1,2]

ANKTIVA is a treatment for use in combination with a standard treatment for NMIBC, Bacillus Calmette-Guérin (BCG), for people with NMIBC for whom BCG alone was not effective or in whom NMIBC returned after initial successful treatment. These people have what is termed BCG-unresponsive NMIBC.

Who Qualifies to Receive ANKTIVA?

ANKTIVA is a treatment for adults who have all of the following:

- High-risk NMIBC CIS
- NMIBC that did not or is no longer responding to BCG therapy alone (BCG-unresponsive)
- NMIBC that has not grown beyond the inner lining of the bladder to the muscle underneath (called carcinoma in situ or CIS disease)
- NMIBC with or without small finger-like tumor growths that project away from the bladder wall into the bladder (papillary disease)

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What is ANKTIVA used for?

ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

When should I not take ANKTIVA?

ANKTIVA is for adults. You should not be treated with ANKTIVA if you are pregnant because it could cause fetal harm. If you could become pregnant, use effective contraception during treatment with ANKTIVA and one week after the last dose.

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What is Non-Muscle Invasive Bladder Cancer and How is it Treated?

The bladder is a hollow, balloon-like organ where urine is stored. NMIBC is bladder cancer that has grown on the lining of the bladder, but has not spread past the innermost surface of the bladder to the muscle underneath. It is the most common type of bladder cancer.

4 out of 5 people with bladder cancer have NMIBC[3]

For NMIBC that is likely to keep growing (intermediate or high risk), BCG is a common first therapy. But for an estimated 30 to 40 percent of patients, BCG therapy may not work long term.[4] If BCG therapy doesn't work or stops working, there are only a few approved treatment options to try before surgical removal of the bladder is recommended. But there are reasons for people with BCG-unresponsive NMIBC to feel hopeful—a treatment approved by the U.S. FDA in April 2024, which may help them keep their bladder: ANKTIVA plus BCG.

If You Have Been Diagnosed with BCG-Unresponsive NMIBC CIS Disease and are Interested in ANKTIVA®, Here is What You Need to Know:

What is ANKTIVA?

It is important for you to learn all you can about ANKTIVA as a treatment option, including how it works, how it was studied, and what to expect before, during, and after treatment. Here are a few quick facts about ANKTIVA to help.

Discuss your treatment options with your healthcare team and work closely with them to create a treatment plan that is suitable for you.

What ANKTIVA is

- ANKTIVA is an immunotherapy that activates your body's natural immune system
- ANKTIVA is used in combination with BCG and is administered directly into your bladder via a catheter
- ANKTIVA is the first treatment of its type approved to treat BCG-unresponsive NMIBC
- ANKTIVA can be administered in a clinical setting and allows you to remain in the care of your urologist

What ANKTIVA is not

- ANKTIVA ***is not*** a chemotherapy or gene therapy
- ANKTIVA ***is not*** administered via an IV. It only fights cancer in the bladder. This may reduce side effects.
- ANKTIVA ***is not*** a chemical, it is a biologic that is similar to molecules found naturally in the body
- ANKTIVA does not require you to change providers for treatment

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What warnings should I know about ANKTIVA?

Risk of Metastatic Bladder Cancer with Delayed Cystectomy. Delaying cystectomy can lead to the 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 a second induction course of ANKTIVA with BCG, reconsider cystectomy.

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How is ANKTIVA® Administered?

ANKTIVA and BCG are combined in one syringe and administered directly into the bladder through a tube called a catheter. The procedure is performed by a urologist (or qualified health care provider) once a week for six weeks. This is the same process as when BCG is administered alone. The post-treatment directions are like those for after BCG treatment as well. Learn more about the steps you need to take on page 5. A second treatment course may be administered if the tumor does not shrink at three months.

ANKTIVA is given by a urologist or other healthcare provider in their clinic. The urologist will also manage care after treatment, so conveniently, your healthcare team remains the same.

How was ANKTIVA plus BCG Studied and What Were the Results?

A type of clinical trial called a phase 2/3 study was conducted to assess the ability of ANKTIVA (also known as nogapendekin alfa inbakicept (NAI) or N-803) plus BCG to successfully treat people with BCG-unresponsive NMIBC CIS disease. In these participants, ANKTIVA plus BCG treatment was well-tolerated and effective.[5]

Safety – Adverse Reactions (side effects)

In the 88 study participants who qualified for safety analysis, most Side Effects were mild and manageable (fatigue, nausea, bladder irritation, and diarrhea) and went away after 2 days.

16% of people taking ANKTIVA had serious side effects

7% of study participants had to stop ANKTIVA due to side effects

Effectiveness

In the 77 study participants who qualified for analysis of efficacy:

62% had a complete response, which is successful treatment of NMIBC

58% of the participants with a complete response stayed NMIBC-free for a year or longer

40% of participants with a complete response remained NMIBC-free at two years

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What to Consider Before Taking ANKTIVA®

Let your healthcare provider know:

- If you have an allergy to any ingredient in ANKTIVA, discuss this with your healthcare provider.
- All medicines and supplements 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(s), be sure to alert your healthcare provider as early as possible and schedule another appointment at a time that works for you

What Should You Expect When Taking ANKTIVA?

During your treatment you should:

- **Wear comfortable clothes. The treatment will last for at least 1 hour, and you will need to hold the medicine in your bladder for two hours after it is administered.**
- **Avoid using the restroom until your treatment is done.**
- **Let your healthcare provider know if you have any cramping or feel like you urgently need to urinate.**

After your treatment:

- **For the first 24 hours following treatment, your urine may have a red color, which may be blood in the urine. Report any prolonged red-colored urine to your healthcare provider.**
- **You may experience discomfort, pain, or burning when urinating; if these symptoms persist, report them to your healthcare provider.**
- **Be sure to drink water (stay hydrated) following treatment.**
- **Schedule your next appointment, which is the following week if you are receiving the once-a-week treatment for 6 weeks, and at about 3 months from the first dose.**

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

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What to Expect After ANKTIVA® Treatment

Important things to know after receiving your first dose:

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

- fatigue
- nausea
- discomfort when urinating
- diarrhea
- blood (red color) in your urine

These are not all the possible side effects of ANKTIVA. 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 ANKTIVA at 1-877-ANKTIVA (1-877-265-8482).

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Other important Things to Consider:

- Because ANKTIVA plus BCG is administered once a week for 6 weeks, plan to be able to go to your health care provider's clinic during this time period.
- After your first 6-week round of treatment, your doctor will want to monitor how well ANKTIVA is working, typically at 12 weeks (3 months) from the start of treatment.
- If your NMIBC is not completely gone, you and your doctor may decide to try a second 6-week round of treatment, this is called re-induction.
- To ensure ANKTIVA plus BCG keeps working, maintenance treatments are recommended. These occur once a week for 3 weeks at about 4, 7, 10, 13 and 19 months after the first dose. Additional maintenance at months 25, 31, and 37 may be administered for patients with ongoing response.
- Before treatment and after treatment to see if ANKTIVA plus BCG is working, your healthcare professional will typically use a cystoscope - a thin, tube-like instrument with a light that allows the doctor to view the inside of your bladder – to look for bladder cancer. They may also take a sample of tissue for study to see if the cancer is gone.

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What are the side effects of ANKTIVA?

The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, pain with urination, urinary frequency, urinary urgency, blood in the urine, urinary tract infection, increased potassium, musculoskeletal pain, chills, and fever.

For more information about ANKTIVA, please see the Full Prescribing Information at www.Anktiva.com.

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 ImmunityBio at **1-877-ANKTIVA** (1-877-265-8482).

What should I tell my health care provider?

Before treatment with ANKTIVA, tell your doctor if you are pregnant or suspect that you may be pregnant.

After treatment with ANKTIVA, tell your doctor if irritable bladder symptoms or passage of red-colored urine lasts longer than 24 hours.

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ImmunityBio is Here to Support You Throughout Your Treatment

The ImmunityBio CARE™ program is designed to help patients access ImmunityBio's innovative treatment for BCG-unresponsive NMIBC CIS. The program offers services and resources to determine if your insurance covers ANKTIVA®, including benefits investigation, prior authorization support and tracking, coding and billing assistance, claim denial guidance and payer specific appeal assistance.

More information for patients and healthcare professionals is available on Anktiva.com or **1-877-ANKTIVA (1-877-265-8482)**.

References

1. Chamie, K. et al. IL-15 Superagonist NAI in BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer. New England Journal of Medicine (NEJM) Evidence. 2023 Jan;2(1):EVIDoa2200167. https://pubmed.ncbi.nlm.nih.gov/38320011/
2. U.S. Food and Drug Administration (FDA). FDA approves nogapendekin alfa inbakicept-pmln for BCG-unresponsive non-muscle invasive bladder cancer. U.S. FDA April 2024. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nogapendekin-alfa-inbakicept-pmln-bcg-unresponsive-non-muscle-invasive-bladder-cancer
3. Grabe-Heyne, K. et al. Intermediate and high-risk non-muscle-invasive bladder cancer: an overview of epidemiology, burden, and unmet needs. Frontiers in Oncology Jun 2 2023; 13: 1170124. doi: 10.3389/fonc.2023.1170124. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10272547/
4. Kodera, A. et al. The Management of Bacillus Calmette-Guérin (BCG) Failure in High-Risk Non-muscle Invasive Bladder Cancer: A Review Article. Cureus. 2023 Jun; 15(6): e40962. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10369196/
5. ANKTIVA Package insert. ImmunityBio, Inc.; 2024.

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