PRESCRIBING INFORMATION
Refer to the Summary of Product Characteristics (SmPC) before prescribing.

ANKTIVA▼(nogapendekin alfa inbakicept) 400 micrograms concentrate for intravesical solution**.**

PRESENTATION: Single-dose vial containing 400 micrograms nogapendekin alfa inbakicept in 0.4 mL solution (1 mg/mL). Each vial contains less than 1 mmol potassium (39 mg) and less than 1 mmol sodium (23 mg)

INDICATION: In combination with Bacillus Calmette-Guérin (BCG) for adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.

DOSAGE AND ADMINISTRATION: Induction: 400 micrograms intravesically with BCG once a week for 6 weeks. A second induction course may be administered if complete response is not achieved at month 3. **Maintenance:** 400 micrograms intravesically with BCG once a week for 3 weeks at months 4, 7, 10, 13 and 19 (for a total of 15 doses). For patients with ongoing complete response at month 25 and later, maintenance instillations with BCG may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations**.** Continue treatment until disease persistence after second induction, recurrence or progression, unacceptable toxicity, or a maximum of 37 months. **Method of administration:** For dilution and administration instructions, see SmPC**. and the SmPC of the specific BCG.** The admixture of ANKTIVA in combination with BCG is instilled into the bladder via a catheter which is removed after instillation. Do not repeat the dose if the patient voids before 2 hours.

CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS: <u>For Intravesical Use Only. Do not administer ANKTIVA by subcutaneous or intravenous or intramuscular routes.</u> Risk of metastatic bladder cancer with delayed cystectomy**:** In patients with BCG-unresponsive CIS, delaying cystectomy could lead to development of muscle invasive or metastatic bladder cancer. Risk increases the longer cystectomy is delayed in the presence of persisting CIS. In patients with CIS, reconsider cystectomy if a complete response to treatment after a second induction course of ANKTIVA with BCG is not achieved. The possibility of severe systemic BCG-infections with the necessity of anti-tuberculosis therapy should be considered before initiating the BCG-therapy. **Traceability:** Clearly record the name and batch number of the administered product.

PREGNANCY AND LACTATION: Women of childbearing potential: Verify pregnancy status prior to initiating treatment. Advise females of reproductive potential to use effective contraception during treatment and for 1 week after the last dose. **Pregnancy**: Systemic exposure following intravesical administration is negligible. No effects during pregnancy are anticipated. Based on its mechanism of action, ANKTIVA may cause foetal harm if systemic exposure occurs. No available data in pregnant women. **Breast-feeding**: Can be used during breast-feeding as systemic exposure following intravesical administration is negligible.

UNDESIRABLE EFFECTS: Very Common (≥ 1/10): Urinary tract infection, dysuria, pollakiuria, haematuria, micturition urgency, musculoskeletal pain, fever, chills, pyrexia. **Common (≥1/100 to <1/10):** Cystitis, Bacteriuria, Bacteraemia, Sepsis, Anaemia, Leucocytosis, Lymphadenopathy, Decreased appetite, Dehydration, Dizziness, Headache, Dyspnoea, Diarrhoea, Nausea, Abdominal pain, Constipation, Vomiting, Night sweats, Pruritus, Rash, Myalgia, Arthralgia, Muscular weakness, Bladder spasm, Cystitis noninfective, Nocturia, Urinary incontinence, Urinary tract pain, Urinary retention, Bladder pain, Urge incontinence, Lower urinary tract symptoms, Urinary hesitation, Urine flow decreased, Leukocyturia, Genital pain, Prostatitis, Benign prostatic hyperplasia, Influenza like illness, Chest pain, Blood creatinine increased, Cancer cells present in urine.

Presentation and Price: £28,000 per vial

Legal Category: POM

Marketing Authorisation Number: PL 59840/0001

Marketing Authorisation Holder: ImmunityBio Ireland Limited, 6th Floor, 2 Grand Canal Square, Dublin 2, D02 A342, Ireland

Date of preparation: August 2026

Document number: UK-Onc-Ankt-01427

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to lmmunityBio at 1-877-ANKTIVA (1-877-265-8482).