**ABBREVIATED PRESCRIBING INFORMATION**

Refer to the Summary of Product Characteristics (SmPC) for full details before prescribing.

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

**▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See below on how to report adverse reactions.**

**PRESENTATION:** Single-dose vial containing 400 micrograms nogapendekin alfa inbakicept in 0.4 mL solution (1 mg/mL).

**INDICATION:** Indicated in combination 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 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 instructions, see SmPC Section 6.6**.** 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. Refer to the SmPC for full administration instructions and to the BCG SmPC for information on bladder retention and patient positioning.

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

**SPECIAL WARNINGS AND PRECAUTIONS: For Intravesical Use Only. Do NOT administer ANKTIVA by subcutaneous or intravenous or intramuscular routes. 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, which can be lethal. 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. **Traceability:** Clearly record the name and batch number of the administered product. **Excipients:** Contains less than 1 mmol potassium (39 mg) and less than 1 mmol sodium (23 mg) per dose, i.e. essentially "potassium-free" and "sodium-free".

**FERTILITY, PREGNANCY AND LACTATION: Women of childbearing potential:** Verify pregnancy status prior to intiating 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 fetal 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. **Fertility**: No clinical data available.

**UNDESIRABLE EFFECTS:** Refer to Section 4.8 of the SmPC for complete information on side effects. **Very Common (≥ 1/10):** Dysuria, pollakiuria, haematuria, micturition urgency, fatigue. **Common (≥1/100 to <1/10):** Urinary tract infection, cystitis, decreased appetite, dehydration, headache, dyspnoea, diarrhoea, nausea, abdominal pain lower, vomiting, night sweats, pruritus, rash, arthralgia, muscular weakness, myalgia, arthritis, flank pain, pain in extremity, bladder spasm, cystitis noninfective, nocturia, urinary tract pain, incontinence, urinary incontinence, urinary retention, urinary tract discomfort, bladder irritation, lower urinary tract symptoms, polyuria, urge incontinence, urinary hesitation, urine abnormality, prostatitis, benign prostatic hyperplasia, penile discharge, penile pain, vulvovaginal burning sensation, chills, pyrexia, influenza like illness, pain, suprapubic pain, bacterial test positive, blood urine present, blood creatinine increased, cells in urine, blood urea increased, glomerular filtration rate decreased.

**Legal Category:** POM. **Price:** Under Consideration **Marketing Authorisation Number:** PL 59840/0001; 1 single-dose vial. **Marketing Authorisation Holder:** ImmunityBio Ireland Limited, 6th Floor, 2 Grand Canal Square, Dublin 2, D02 A342, Ireland
**Date of revision**: March 2026 **Job Code:** ANK-260052-UK-v1.0

**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)**