

ANKTIVA® is Co-Administered with BCG – For Familiar Storage and Dosing

Administration of ANKTIVA with BCG maintains the same favorable workflow and schedule as that of BCG in the urology practice environment.

Preparation of BCG and ANKTIVA Admixture

For Intravesical Use Only. Do NOT administer by subcutaneous or intravenous or intramuscular routes.

Step 1

BCG Diluted in 50 mL Saline

Prepare BCG suspension following the instructions provided in the Prescribing Information for BCG with saline as follows:

Draw 1 mL of sterile, preservative-free saline (0.9% Sodium Chloride Injection USP) from a 50 mL vial of sterile saline at 4-25°C into a small syringe (e.g., 3 mL) and **add to 1 vial of BCG to resuspend**. Ensure that the needle is inserted through the center of the rubber stopper of the vial. Gently swirl the vial until a homogenous suspension is obtained. Avoid forceful agitation which may cause clumping of the mycobacteria.

Dilute the cloudy BCG suspension in the same 50 mL sterile, preservative-free saline vial to **a final volume of 50 mL**. Mix the suspension gently prior to step 2.



Step 2

Anktiva Admixed in 50 mL Saline with BCG

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution is clear to slightly opalescent and colorless to slightly yellow. Discard the vial if visible particles are observed.

Draw 0.4 mL of ANKTIVA into a small syringe and using aseptic technique **add to the 50 mL saline volume containing the BCG suspension** from step 1 that has been prepared following the instructions provided in the Prescribing Information for BCG.

Mix the suspension gently.



Step 3

50 mL Admixed Volume Transferred to 60 mL Syringe

Using a **60-mL syringe** connected to an appropriate size needle, withdraw the ANKTIVA BCG mixture to a final volume of 50 mL.

If the admixture of ANKTIVA in combination with BCG is not used immediately, store refrigerated at 2°C to 8°C (36°F to 46°F) and use within 2 hours. Unused solution of admixture should be discarded after 2 hours.



Intravesical Administration

Step 1

Insert foley catheter under standard sterile conditions.

Step 2

Connect 60 mL syringe to foley catheter and infuse gently.

Step 3

The ANKTIVA and BCG admixture to remain in the bladder for two-hours. Patients unable to retain the suspension for 2 hours should be allowed to void sooner, if necessary. Do not repeat the dose if the patient voids before 2 hours.



Storage of ANKTIVA

ANKTIVA is stored at 2°C to 8°C (36°F to 46°F) and not frozen.

Do not shake.



Open your camera and point your smart device at the QR code to access Anktiva.com

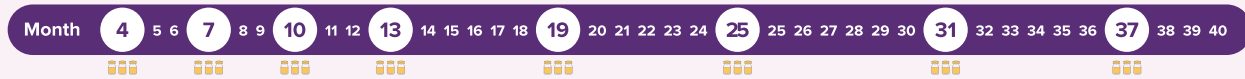
Intravesical Instillation Schedule of ANKTIVA®

FIRST INDUCTION



■ ANKTIVA 400 mcg administered intravesically with BCG once a week for 6 weeks. A second induction course is not required if a complete response is achieved at month 3. Cystoscopy and cytology performed for drug administration every three months and follow-up per office practice.

MAINTENANCE



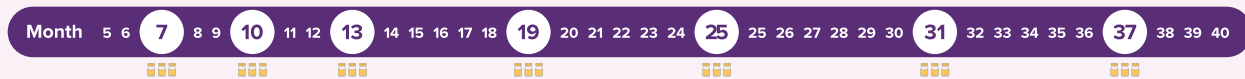
For Maintenance: After BCG and ANKTIVA induction therapy, ANKTIVA is recommended at a dose of 400 mcg administered intravesically with BCG once a week for 3 weeks at months 4, 7, 10, 13 and 19 (for a total of 15 doses). For patients with an ongoing complete response at month 25 and later, maintenance instillations may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations.

FIRST & SECOND INDUCTION



■ ANKTIVA 400 mcg administered intravesically with BCG once a week for 6 weeks. A second induction course is not required if a complete response is achieved at month 3. Cystoscopy and cytology performed for drug administration every three months and follow-up per office practice.

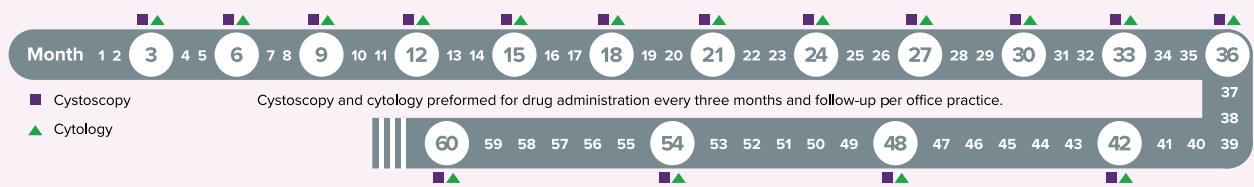
MAINTENANCE



For Maintenance: After BCG and ANKTIVA induction therapy, ANKTIVA is recommended at a dose of 400 mcg administered intravesically with BCG once a week for 3 weeks at months 7, 10, 13 and 19 (for a total of 15 doses). For patients with an ongoing complete response at month 25 and later, maintenance instillations may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations.

Cystoscopy Schedule, Follow-Up and Long-Term Follow-Up (5 Years)

PROCEDURE SCHEDULE: EVERY THREE MONTHS



INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guerin (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. **WARNINGS AND PRECAUTIONS: 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. **DOSAGE AND ADMINISTRATION: For Intravesical Use Only.** Do not administer by subcutaneous or intravenous routes. Instill intravesically only after dilution. Total time from vial puncture to the completion of the intravesical instillation should not exceed 2 hours. **USE IN SPECIFIC POPULATIONS: Pregnancy:** May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. **ADVERSE REACTIONS:** The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills and pyrexia.

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).