General Clinical Practice

Use of Nadofaragene Firadenovec-vncg: A Practical Guide for Nurses

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Abstract

Nadofaragene firadenovec-vncg (Adstiladrin®) is an intravesical nonreplicating adenoviral vector-based gene therapy indicated in high-risk Bacillus Calmette-Guérin-unresponsive non-muscle-invasive bladder cancer with carcinoma in situ with or without papillary tumors. This review provides nursing considerations regarding nadofaragene firadenovec, including proper storage and handling, administration protocols, monitoring for adverse events, appropriate disposal, and patient education.

Keywords

Bacillus Calmette-Guérin-unresponsive non-muscle-invasive bladder cancer, gene therapy, urologic oncology, nadofaragene firadenovec-vncg, bladder cancer, intravesical therapy, clinical nursing practice

Disease Burden

Bladder cancer is a prevalent disease globally, ranking as the 9th most common cancer worldwide. Within the United States, there will be an estimated 83,190 new cases diagnosed in 2024, making it the sixth most common cancer (Bray et al., 2024; National Cancer Institute, 2019; Siegel et al., 2024). Bladder cancer is three to four times more common in men than women and largely affects older adults, with a median age at diagnosis of 73 years (National Cancer Institute, 2019). Smoking is a well-established risk factor, along with certain occupational exposures (Freedman et al., 2011; Holzbeierlein et al., 2024). Most bladder cancer cases (approximately 75%) are categorized as non-muscle-invasive bladder cancer (NMIBC), a category of urothelial carcinoma that does not extend into or beyond the muscle layers of the bladder wall (Babjuk et al., 2017; Holzbeierlein et al., 2024). NMIBC staging encompasses Ta, T1, and carcinoma in situ (CIS), with histologic classification including low-grade or high-grade disease (Babjuk et al., 2017; Holzbeierlein et al., 2024; National Comprehensive Cancer Network, 2024). High-grade NMIBC is more likely to progress and involve muscle layers of the bladder wall, carrying a less favorable prognosis. Risk stratification methods account for stage, grade, previous therapies, and tumor size (among other factors) and allow the stratification of patients into low-, intermediate-, or high-risk groups (Holzbeierlein et al., 2024). This stratification assists in guiding individualized treatment decisions surrounding workup, therapy choice, and monitoring in patients with NMIBC (Holzbeierlein et al., 2024; National Comprehensive Cancer Network, 2024).

Treatment of NMIBC

Management of NMIBC requires a multidisciplinary approach involving physicians, advanced practice providers, pharmacists, nurses, and other health care team members working collaboratively to enable optimal patient care (Selby et al., 2019). As part of the multidisciplinary team, nurses have vital roles in NMIBC treatment, including administering therapies, monitoring and educating patients, assessing and managing adverse events (AEs), providing supportive care, and maintaining accurate documentation.

An initial transurethral resection of the bladder (TURBT) is required for staging, grading, and diagnosis; a repeat TURBT within 6 weeks is recommended in select patients. TURBT is typically followed by intravesical Bacillus Calmette-Guérin (BCG) or, more rarely, radical cystectomy in patients with high-risk disease, depending on risk factors, comorbidities, and patient preferences (Babjuk et al., 2017; Holzbeierlein et al., 2024; National Comprehensive Cancer Network, 2024). Intravesical BCG immunotherapy is a live attenuated bacterium that relies on adaptive and innate immune responses to exert its antitumor effects and has been

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Competing Interests:
Jennifer Sutton: Served as a consultant for Janssen and Sesen Bio. Served as an advisor on an advisory board for Bayer and Merck. Serves on a speaker bureau for Bayer.

Abbreviations

AE	Adverse event
BCG	Bacillus Calmette-Guérin
CIS	Carcinoma in situ
CSTD	Closed-system transfer device
NMIBC	Non-muscle-invasive bladder cancer
TURBT	Transurethral resection of the bladder

used for several decades in treating bladder cancer (Shelley et al., 2000). While initial complete response rates with BCG are high (up to 80%), up to half of patients will eventually experience recurrence and/or progression of NMIBC during long-term follow-up (Cookson et al., 1997; Daniels et al., 2020; Lamm et al., 2000; Lerner et al., 2015). The US Food and Drug Administration (FDA) defines BCG-unresponsiveness as at least one of the following: (1) persistent or recurrent CIS alone or with recurrent Ta/T1 disease within 12 months of completion of adequate BCG therapy; (2) recurrent high-grade Ta/T1 disease within 6 months of completion of adequate BCG therapy; or (3) high-grade T1 disease at the first evaluation following an induction BCG course. Adequate BCG therapy is defined as at least 5 of 6 induction doses and 2 of 3 maintenance treatments, or at least 2 of 6 instillations of a second induction course in which maintenance BCG is not given (US Department of Health and Services, 2018). Failure to achieve a complete response after initial treatment with BCG is associated with poor outcomes, as is recurrence and progression of disease following an initial response (Li et al., 2019).

Radical cystectomy is often recommended in the setting of high-risk BCG-unresponsive NMIBC; however, it is a major surgery typically requiring removal of the bladder, prostate, and seminal vesicles in men or the bladder, uterus, fallopian tubes, and anterior vagina in women (Lenis et al., 2020). There is considerable risk of morbidity, mortality, and decreased quality of life following radical cystectomy. The risks of negative outcomes are higher among older patients, and NMIBC often presents at an advanced age where radical cystectomy may not be preferred or feasible. Given the significant potential challenges associated with radical cystectomy, many patients may elect for bladder-preserving therapies following shared decision-making with their health care team (Collacott et al., 2023). For patients with BCG-unresponsive NMIBC who are not suitable for or who otherwise decline radical cystectomy, there is a need for well-tolerated, effective, bladder-preserving treatment options.

Nadofaragene Firadenovec-vncg for Patients with BCG-Unresponsive NMIBC

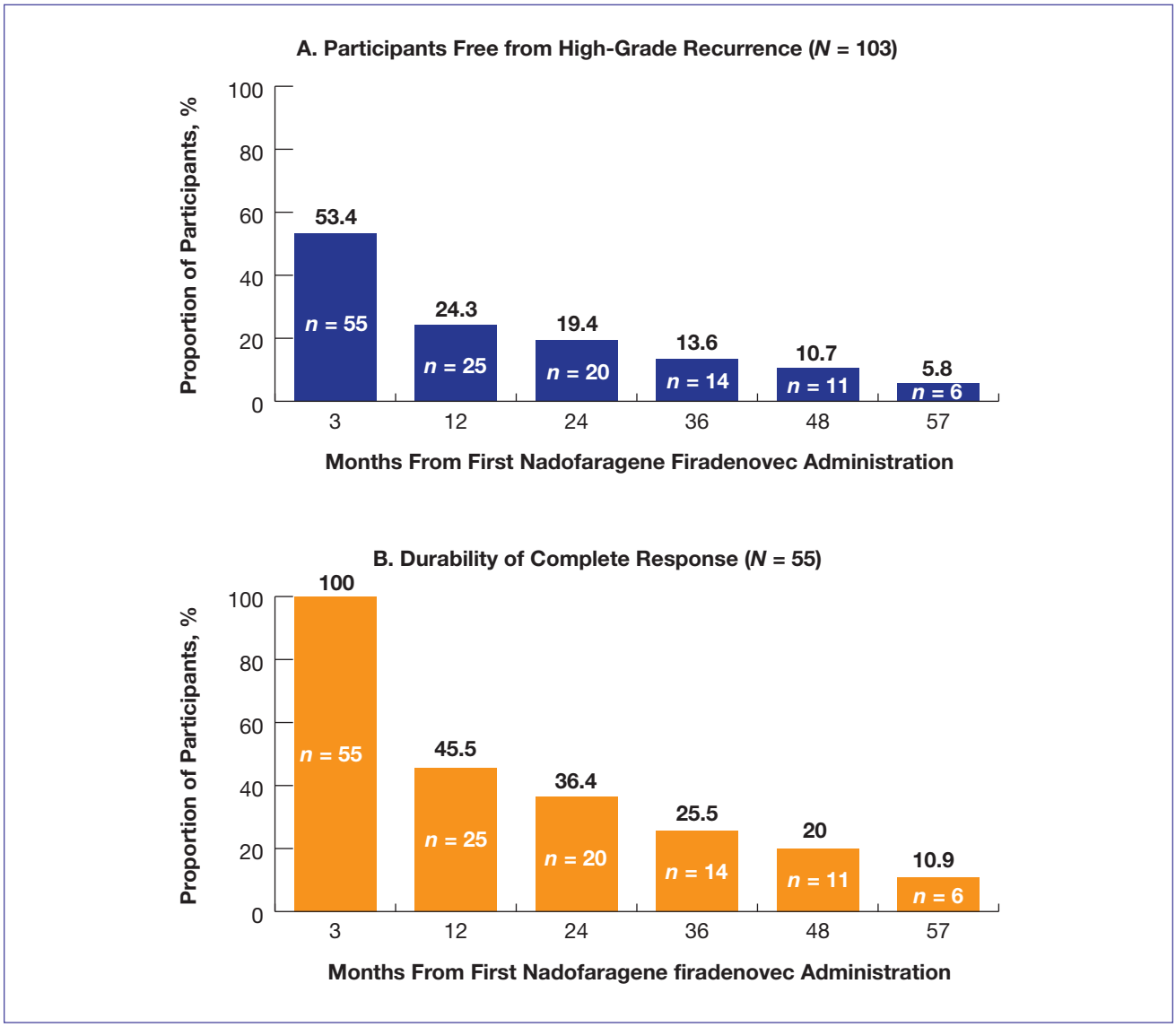
Nadofaragene firadenovec-vncg (Adstiladrin®; nadofaragene or rAd-IFN/Syn3) was approved by the FDA in December 2022 for the treatment of adults with high-risk BCG-unresponsive NMIBC with CIS with or without papillary tumors (± Ta/T1) (Ferring Pharmaceuticals, 2022). Nadofaragene firadenovec is an intravesical nonreplicating adenovirus vector-based gene therapy. It is classified as gene therapy as it delivers a therapeutic transgene, specifically the gene encoding human interferon alpha-2b (IFNα-2b), directly to both benign and malignant urothelial cells. Expression of the IFNα-2b protein promotes anticancer and immunemodulatory effects (Narayan, Meeks, et al., 2024). Nadofaragene firadenovec is administered as a 75-mL intravesical instillation once every 3 months (Ferring Pharmaceuticals, 2022).

In the single-arm, multicenter, open-label, repeat-dose, phase 3 CS-003 study (NCT02773849), among the CIS ± high-grade Ta/T1 cohort (n = 103), 55 participants (53.4%) had a complete response at 3 months after a single instillation of nadofaragene firadenovec. Among these 55 participants with an initial complete response, the response was maintained in 25 participants (45.5%), 20 participants (36.4%), 14 participants (25.5%), and six participants (10.9%) through 12, 24, 36, and 57 months, respectively (Figure 1). In participants with high-grade Ta/T1 disease only without CIS (n = 48), 35 participants (72.9%) were free of high-grade recurrence at 3 months after a single instillation of nadofaragene firadenovec. Among these 35 participants who remained free of high-grade recurrence at month 3, 21 participants (60.0%), 16 participants (45.7%), 11 participants (31.4%), and 7 participants (20.0%) remained free of high-grade recurrence through 12, 24, 36, and 57 months, respectively. Nearly half of all 103 participants (49%, 95% CI [40.0, 57.1]) achieved cystectomy-free survival at 60 months (CIS ± Ta/T1: 43%, 95% CI [32.2, 53.7]; high-grade Ta/T1: 59%, 95% CI [43.1, 71.4]). For most participants, AEs were transient and classified as either grade 1 or 2. Through 5 years after the first instillation of nadofaragene firadenovec, no grade 4 or 5 study drug-related AEs were reported, no deaths were attributed to nadofaragene firadenovec, and only 3 participants (1.9%) discontinued treatment due to study drug-related AEs (Boorjian et al., 2021; Narayan, Boorijan et al., 2024). Nadofaragene firadenovec represents a therapeutic option with a novel mechanism of action and favorable clinical profile in patients with high-risk BCG-unresponsive NMIBC.

Practical Considerations for Nadofaragene Firadenovec Use

Nurses play key roles in the safe and effective administration of nadofaragene firadenovec, including administration, monitoring, supportive care, and patient education. Successful instillation of nadofaragene firadenovec requires understanding its transportation, storage, and administration requirements. While urology clinics and health care team members will have familiarity with the administration of intravesical thera-

Figure 1.
(A) Proportion of Participants Free from High-Grade Recurrence and (B) Durability of Complete Response Among Participants Who Achieved a Complete Response at Month 3, in Those with CIS ± Ta/T1 in the Phase 3 Study (CS-003)



pies, there is an increasing reliance on infusion centers that may be less familiar with the processes of intravesical instillation. Nurses in all settings can learn and promote best practices that increase the likelihood of positive patient experiences and outcomes with using nadofaragene firadenovec. Nurses can proactively identify issues that may arise during instillation, such as potential difficulties with catheterization or challenges voiding urine. It is important to identify any history of recent urologic procedures because instillation within 2 weeks following endoscopic evaluation, biopsy, or TURBT should be avoided to allow sufficient bladder recovery time. Advising the patient to reduce fluid intake several hours before instillation may minimize urine production, facilitating easier retention during the 1-hour dwell time (Babjuk et al., 2017).

Storage and Preparation

Depending on the institution, nurses may be responsible for nadofaragene firadenovec receipt and storage. Nadofaragene firadenovec is delivered and stored frozen and must be thawed and brought to room temperature (20°C to 25°C [68°F to 77°F]) before instil-

lation, as cold fluids may precipitate urinary urgency and bladder spasm. Thawing and bringing nadofaragene firadenovec to room temperature is approximately 8 to 10 hours when thawing in the cardboard nest and approximately 3 to 5 hours when thawing outside the nest. If placed in the refrigerator to thaw, vials will thaw in approximately 4 to 5 hours outside the cardboard nest or in 11 to 13 hours inside the nest. After removing from the refrigerator, the vials will take about 2 hours and 30 minutes to bring to room temperature outside the nest or 6 hours inside the nest. The logistics of thaw time in relation to patient arrival should be considered. Proactively communicate with the care team regarding administration schedules to initiate thawing before patient arrival. Once thawing is initiated, vials may be stored for a maximum of 24 hours at room temperature or up to 7 days refrigerated at 2°C to 8°C (36°F to 46°F); this storage time includes the time it takes to thaw nadofaragene firadenovec. Protect nadofaragene firadenovec from light and do not expose it to elevated temperatures (i.e., above room temperature). Nado-7faragene firadenovec cannot be refrozen once thawed, underscoring the importance of proactive communication between nursing, pharmacy, and other health care team members to avoid potential medication waste (Ferring Pharmaceuticals, 2022).

To prepare for administration of nadofaragene firadenovec, gather all necessary equipment, including four thawed vials, four vented vial adaptors that are suitable for a 20-mL vial, two 50- or 60-mL polypropylene Luer lock syringes (or one Luer lock syringe equal to or greater than 75 mL, with a maximum size of 100 mL), two Luer lock adaptors, and one straight or intermittent urethral catheter with a proximal funnel opening that will accommodate the Luer lock adapter. The urethral catheters should be made of vinyl, polyvinyl chloride, red rubber latex, or silicone; avoid catheters coated or embedded with silver or antibiotics. There is no need for reconstitution or preparation under a biosafety cabinet or laminar flow hood, although some institutions may choose to use these controls if available. Similarly, closed-system transfer devices (CSTDs) are not required to instill nadofaragene firadenovec; however, they may be used per individual institution processes.

All vials should be mixed gently and inspected for visible particles and discoloration. The medication should be clear to opalescent; some opalescent flecks may be visible. Do not use the vials if visible particles or discoloration are seen. Fully thaw nadofaragene firadenovec to room temperature before instillation because cold fluids may cause bladder spasms, as previously noted.

Adhere to the aseptic technique when removing the vial cap and attaching it to a vented vial adaptor per the manufacturer's instructions. Once the vial adaptor has been attached, a syringe should be connected, and the vial contents withdrawn. These steps must be repeated using the remaining three vials until 75 mL has been withdrawn; any remaining volume should be discarded per universal biosafety precautions. If two syringes are used, label each syringe clearly with the number of doses (e.g., "Dose 1 of 2") to ensure the patient receives the full dose of nadofaragene firadenovec. The volume of nadofaragene firadenovec in each syringe does not need to be equal. Nadofaragene should be administered within 6 hours of drawing into a syringe; if not immediately administered, protect the syringe(s) from light (Ferring Pharmaceuticals, 2022).

Medication Safety

Universal biosafety precautions should be observed when handling nadofaragene firadenovec. Individuals with immunosuppressive conditions or taking immunosuppressive medications should avoid contact with nadofaragene firadenovec, including preparation and administration. Immunocompromised or immunodeficient individuals may be at risk for disseminated adenovirus infection due to the potential for low levels of replication-competent adenovirus (Ferring Pharmaceuticals, 2022). Ensure appropriate accommodations are made among the health care team for safe preparation, dispensing, and administering nadofaragene firadenovec.

Nadofaragene firadenovec currently has no known medication interactions. Contraindications include patients with prior hypersensitivity reactions to interferon-alpha or any component of the product; all components of the formulation can be found in the FDA package insert (Ferring Pharmaceuticals, 2022). Ensure nadofaragene firadenovec is only instilled through the intravesical route and follow medication safety best practices to avoid inadvertent intravenous, topical, or oral administration.

Administration and Instillation Considerations

The dose of nadofaragene firadenovec is 75 mL (3×10^{11} viral particles/mL) instilled into the bladder via a urinary catheter once every 3 months. Premedication with an anticholinergic before each instillation of nadofaragene firadenovec may help control symptoms of urinary urgency and other voiding symptoms (Ferring Pharmaceuticals, 2022). Premedication with anticholinergics was recommended but not mandated during the phase 3 CS-003 study. Their use could be omitted per provider preference or if contraindicated.

Because catheterization may prove challenging for some patients, ensure that any medications that may be used during catheterization are available (Wang et al., 2024). Aseptic technique is critical to prevent contamination with microorganisms and lower the risk of infection. Use appropriate personal protective equipment during nadofaragene firadenovec instillation and only use recommended catheters per the prescribing information. The patient's bladder must be completely emptied using this catheter before nadofaragene firadenovec instillation. Once the bladder is empty, 75 mL of room

temperature (20°C to 25°C [68°F to 77°F]) nadofaragene firadenovec may be slowly instilled into the bladder. Confirm that the complete volume is administered from the syringe(s). Instill nadofaragene firadenovec manually from the syringe through the catheter; do not use gravity drainage or any other means of administration.

After instillation, nadofaragene firadenovec should remain in the bladder for 1 hour. If the patient exhibits symptoms of bladder spasm or premature voiding, consider repositioning (Ferring Pharmaceuticals, 2022). Nurses should educate patients on retaining the medication to prevent accidental leakage of nadofaragene firadenovec outside of the bladder. Emphasize the importance of the patient remaining at the administration site for the full 1-hour dwell time. After 1 hour, the patient should void and completely empty their bladder. Voided urine should be disinfected for 15 minutes with an equal volume (approximately half a cup) of virucidal agent (such as sodium hypochlorite with 0.5% active chlorine or 6% hydrogen peroxide solution) before flushing the toilet, and the toilet should not be used by any other individuals during the 15-minute disinfection time (Ferring Pharmaceuticals, 2022).

AE Management

Nursing interventions for managing AEs related to nadofaragene firadenovec administration can be proactive and responsive. Regular monitoring during and after instillation is vital for prompt management of AEs. Nurses should be aware of signs and symptoms related to common AEs, including leakage of nadofaragene firadenovec around the instillation site, bladder spasm, urinary urgency, and fatigue (Boorjian et al., 2021; Narayan, Boorijan et al., 2024). Nurses are often the health care team members with the most direct communication with a patient during the instillation process and can relay patient needs to the prescribing health care team, allowing appropriate supportive care measures to be implemented.

Disposal

There may be medication spillage during catheter removal or if the patient is unable to retain the medication for the prescribed dwell time – nurses should, therefore, be aware of appropriate disposal procedures. Any nadofaragene firadenovec spills should be treated with a virucidal agent for 15 minutes (Ferring Pharmaceuticals, 2022). Disposable materials in contact with nadofaragene firadenovec should be placed in biohazard containers for destruction per institutional policy, and non-disposable equipment may be decontaminated according to individual facility standard operating procedures.

Patient Education and Follow Up

Patient education is a fundamental nursing role. Education on adverse events and post-instillation follow-up may help support the safe and effective use of therapy and alleviate patient concerns. Common AEs include leakage of fluid around the urinary catheter, bladder spasm, urinary urgency, and fatigue. Nurses should assist in educating patients on these AEs, monitoring for signs and symptoms, and managing AEs that may arise.

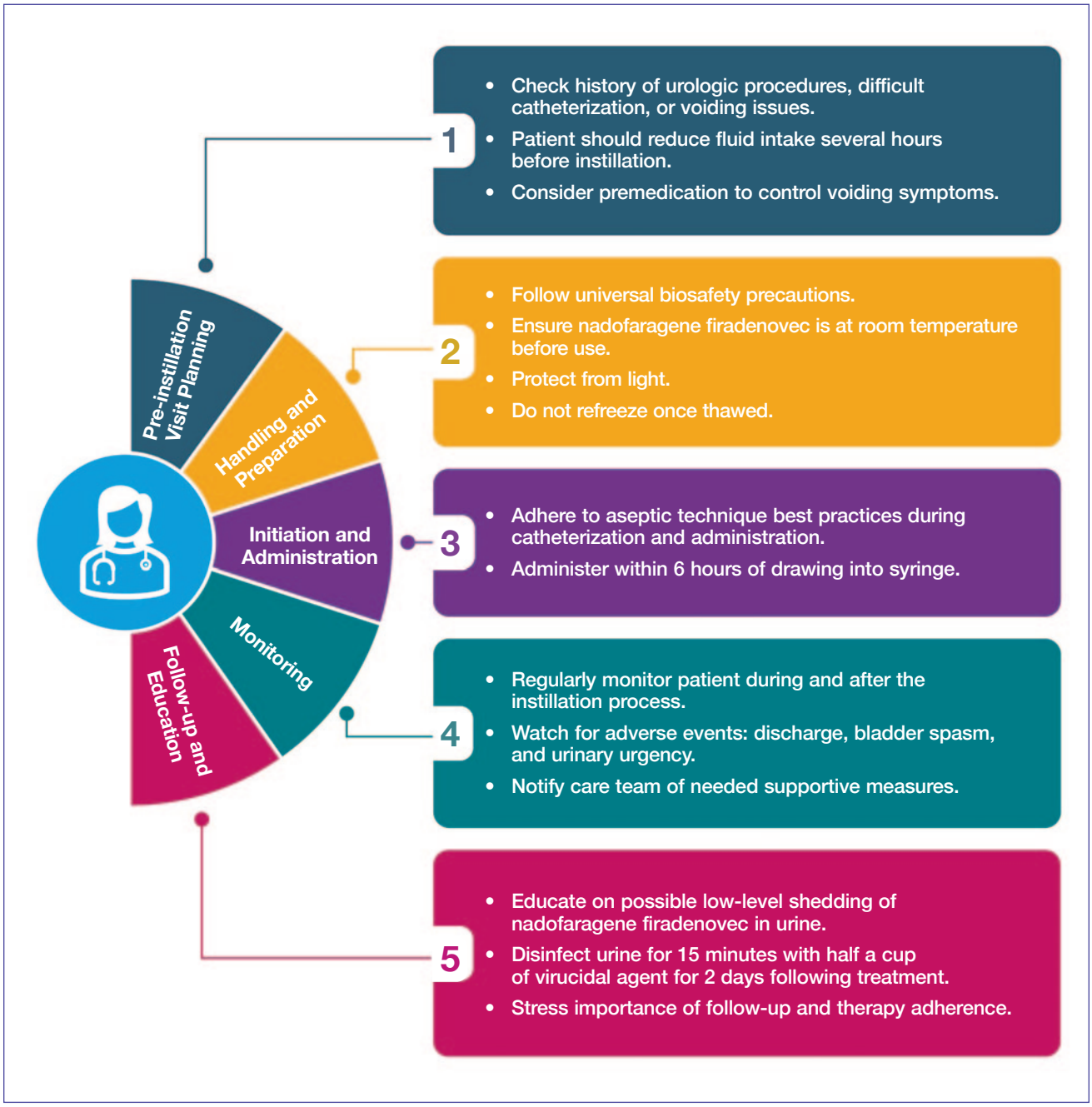
Nurses should inform patients and their caregivers that treatment or contact with nadofaragene firadenovec in those who are immunocompromised, including those receiving immunosuppressive therapy, may increase the risk for disseminated adenovirus infection. Additionally, transient low-level shedding of nadofaragene firadenovec may occur in the urine. Therefore, nurses should instruct patients and their caregivers to disinfect voided urine for 15 minutes before flushing with approximately half a cup of full-strength bleach (sodium hypochlorite with 0.5% active chlorine or 6% hydrogen peroxide solution) for two days following treatment (Ferring Pharmaceuticals, 2022). If possible, no other individuals should use the same toilet the patient uses for the two days following each instillation. If this is not possible, educate that the toilet should not be used by anyone but the patient during each 15-minute disinfection period over the two days.

Educate female patients of reproductive potential on the use of effective contraception during treatment. Effective contraception should be continued for 6 months following the last dose. For male patients, educate those with female partners of reproductive potential to use effective contraception during treatment and for 3 months following the last dose. There are no adequate studies on the teratogenic potential of nadofaragene firadenovec, and no nonclinical or clinical studies were performed to evaluate the effect of nadofaragene firadenovec on fertility. Pregnant women should be advised of the potential risk to a fetus (Ferring Pharmaceuticals, 2022). Emphasize the importance of continued follow-up, therapy schedule adherence, and monitoring to observe for disease recurrence and/or progression. The emotional toll of NMIBC is often significant for patients and family members – offering empathetic care may ease some of the emotional burden patients and their caregivers face.

Summary

Nadofaragene firadenovec is a therapeutic advance for adults with high-risk BCG-unresponsive NMIBC with CIS ± Ta/T1 and represents an additional bladder-preserving therapy option. Nadofaragene firadenovec has demonstrated efficacy and safety across multiple clinical studies, with additional studies underway, including a phase 2 study (ABLE 22; NCT065459550) to evaluate combination therapy with chemotherapy or immunotherapy, a phase 3 study (ABLE-32; NCT06510374) to evaluate use in intermediate-risk NMIBC, and a phase 4 study (ABLE-41; NCT06026332) to explore early utilization and outcomes in the routine care setting.

Figure 2.
Nursing Roles and Responsibilities in Nadofaragene Firadenovec Administration



Nurses in infusion centers and urology clinics are central to patient care and integral to the NMIBC treatment health care team. They are well positioned to effectively integrate nadofaragene firadenovec into a patient's care plan. Nurses should be aware of various aspects of nadofaragene firadenovec use, including its indication, handling and preparation, administration, monitoring, and follow-up; several key points are outlined and summarized in Figure 2. Nurses are equipped to effectively administer nadofaragene firadenovec, evaluate for potential AEs, coordinate with other members of the health care team, and ensure that appropriate supportive care is provided. They also assist in patient and caregiver education and support, advocating for patient needs. As a novel therapy, education regarding nadofaragene firadenovec for nurses is crucial to building comfort and confidence in its use. Comprehensive training programs can help nurses understand the nuances of this novel

Figure 3.
Nursing Checklist for Administration of Nadofaragene Firadenovec

therapy, including its mechanism of action, handling, administration and disposal protocols, and potential adverse events. A checklist of required materials and general protocols for nadofaragene firadenovec administration is included in Figure 3. Nadofaragene firadenovec represents a novel intravesical therapy option for patients with BCG-unresponsive NMIBC with CIS ± Ta/T1, and nurses should be aware of the multiple key roles they play in its effective use.

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