New Drug Overview

Blujepa (gepotidacin)
PDL Category: Antibiotics

Introduction

Disease Background:

- Urinary tract infections (UTI) can include cystitis and pyelonephritis (infection of the kidney/upper urinary tract) (*Gupta 2026*).
  - An uncomplicated urinary tract infection (uUTI) is an infection of the bladder (cystitis, lower urinary tract) in females who are not pregnant and who do not have functional or anatomical abnormalities in the urinary tract or other comorbidities that may lead to a more challenging infection to treat (*Gupta 2026, Orrange et al 2025*).
  - Pyelonephritis is generally characterized as a complicated UTI (cUTI) in clinical practice; however, its category may vary dependent on the professional organization (*Orrange et al 2025*).
- uUTIs and cUTIs are included as the most common infections in outpatients overall (*Orrange et al 2025*).
  - UTIs are more common in women than men.
    - Data suggests about 50-60% of women develop a UTI at some point during their life, although prevalence differs by age.
- The common symptoms of cystitis include dysuria, urinary frequency, urinary urgency, and suprapubic pain. In addition, although not as common, gross hematuria may occur (*Orrange et al 2025*).
- Empiric antibiotic treatment is suitable when there is a robust instinct that a nonpregnant female has acute uUTI (*Orrange et al 2025*).
  - Nitrofurantoin is generally listed as a first-line treatment, along with fosfomycin or pivmecillinam.

- A common sexually transmitted infection (STI) that is treatable includes gonorrhea (*CDC 2025*). However, globally, it is a major cause of morbidity in sexually active individuals (*Ghanem 2026*).
  - Gonorrhea, having an infection with *Neisseria gonorrhoeae* (gram-negative coccus), is the second most frequent communicable disease that is reported in the United States. Furthermore, more than 600,000 cases are reported yearly and it is likely that the same number of cases have yet to be reported.
    - It is a main reason of urethritis in men and cervicitis in women.
- While *N. gonorrhoeae* can infect the rectum and pharynx, the most usual infections accompanied with *N. gonorrhoeae* are genital infections (*Ghanem 2026*).
  - In women, the most frequent location of infection is the uterine cervix. It has been estimated that most (even up to 70 percent) women have no symptoms; however, symptoms generally occur within 10 days of exposure if they are present, which may include vaginal pruritus and/or a mucopurulent discharge.
    - The urethra is another site for possible infection to occur.
  - *N. gonorrhoeae* is also a frequent cause of urethritis in men, while epididymitis may be a complication of gonococcal infection (*Ghanem 2024*).
    - Symptoms that may occur in men include discharge and dysuria.
- Treatment is available to cure gonorrhea infection, although drug-resistant strains of gonorrhea are on the rise (*CDC 2025*).

- Blujepa (gepotidacin) was FDA approved in 2025.

Pharmacology/Usage

- Blujepa (gepotidacin) is a triazaacenaphthylene antibacterial that inhibits Type II topoisomerases including bacterial topoisomerase II (DNA gyrase) and topoisomerase IV, thus inhibiting DNA replication.

Indications

Table 1. Food and Drug Administration Approved Indications

Indication	Blujepa (gepotidacin) [a]
• Indicated in female adult and pediatric patients 12 years of age and older weighing at least 40kg for the treatment of uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii* complex, *Staphylococcus saprophyticus*, and *Enterococcus faecalis*. • Indicated in adult and pediatric patients 12 years of age and older weighing at least 45kg who have limited or no alternative options for the treatment of uncomplicated urogenital gonorrhea caused by susceptible strains of Neisseria gonorrhoeae. Approval of this indication is based on limited clinical safety data for Blujepa.	✔

[a] To reduce the development of drug-resistant bacteria and maintain the effectiveness of Blujepa and other antibacterial drugs, Blujepa should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

(Prescribing information: Blujepa 2025)

- Information on indications, mechanism of action, pharmacokinetics, dosing, safety, and clinical efficacy summary has been obtained from the prescribing information for the individual products, except where noted otherwise.

Dosing and administration

Table 2. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Blujepa (gepotidacin)	Film Coated Tablets	PO	*uUTI*: BID (about 12 hours apart) for 5 days. *Uncomplicated urogenital gonorrhea:* Initial dose PO, followed by a second dose about 12 hours later. Do not increase the dose, extend the duration of treatment, or reduce the interval between doses due to the risk of QTc interval prolongation.	• Take after a meal to reduce the chance of GI intolerance. • If a dose is missed, instruct patients to take the missed dose as soon as possible. Do not double the dose to make up for a missed dose. • Avoid use with severe renal impairment or kidney failure, including those receiving dialysis. • Avoid use with severe hepatic impairment.

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
				• Additional recommendations for patients with uncomplicated urogenital gonorrhea with moderate renal or moderate hepatic impairment includes to avoid use of Blujepa when additional risk factors for increased gepotidacin exposure are present.

See the current prescribing information for full details.

Clinical Efficacy Summary

- The efficacy of Blujepa was assessed in two multicenter, randomized, parallel-group, double-blind, double-dummy, non-inferiority (NI) trials (Trial 1 and Trial 2) that included female patients (N=3,136) with uUTI.
  - Both trials compared Blujepa 1,500mg (administered orally twice daily with food for 5 days) to nitrofurantoin 100mg (administered orally twice daily for 5 days).
  - Patients entered the trials with at least 2 symptoms consistent with uUTI (dysuria, frequency, urgency, or lower abdominal pain) and with evidence of urinary nitrite or pyuria.
    - Patients with any medical condition or presentation suggestive of a complicated UTI, or an upper UTI (eg, pyelonephritis, urosepsis) were excluded.
- *In Trial 1*, the microbiological ITT nitrofurantoin-susceptible (micro-ITTS) population consisted of female patients (N=634) with uUTI (Blujepa N=336; nitrofurantoin N=298).
  - The median age of patients was 54 years, with 57% being >50 years of age. In addition, 84% were White, 40% had a history of recurrent infection, and the US enrolled the greatest percentage of patients (39%). Patient demographic and baseline characteristics were generally balanced between treatment groups.
- *In Trial 2*, the micro-ITTS population consisted of female patients (N=567) with uUTI (Blujepa N=292; nitrofurantoin N=275).
  - The median age of patients was 51 years, with 52% being >50 years of age. In addition, 85% were White, 41% had a history of recurrent infection, and the majority of patients (67%) were enrolled from the US. Patient demographic and baseline characteristics were generally balanced between treatment groups.
- Efficacy was assessed as a composite of clinical cure and microbiological response at the Test-of-Cure (TOC) visit (study day 10 to 13) in the micro-ITTS population, which included all patients who received at least 1 dose of study medication, had at least one baseline qualifying uropathogen, and excluded patients with organisms not susceptible to nitrofurantoin.
  - Clinical cure was defined as resolution of all signs and symptoms of acute cystitis present at baseline and no new signs and symptoms without the patient receiving other systemic antimicrobials.
  - Microbiological response was defined as having all qualifying uropathogens found at baseline at $\geq 10^5$ colony-forming units (CFU)/ml reduced to $<10^3$ CFU/ml without the patient receiving other systemic antimicrobials.
  - Results suggested that both trials demonstrated NI of Blujepa to nitrofurantoin for composite response.
  - Results are presented in the table below, which was adapted from the prescribing information.

Table 3. Efficacy results

	Blujepa n/N (%)	Nitrofurantoin n/N (%)	Treatment Difference
Trial 1			
Composite Response	174/336 (51.8%)	140/298 (47%)	5.3
Clinical Cure	224/336 (66.7%)	196/298 (65.8%)	1.5
Microbiological Response	244/336 (72.6%)	199/298 (66.8%)	6.0
Trial 2			
Composite Response	172/292 (58.9%)	121/275 (44%)	14.4
Clinical Cure	199/292 (68.2%)	175/275 (63.6%)	4.3
Microbiological Response	213/292 (72.9%)	158/275 (57.5%)	15.5

- The table below presents the composite response rates at the TOC visit for the most common baseline uropathogens across both trials in the micro-ITTS population.

Table 4. Efficacy results

Pathogen	Blujepa n/N (%)	Nitrofurantoin n/N (%)
Escherichia coli	312/566 (55.1%)	234/520 (45%)
Klebsiella pneumoniae	6/14 (42.9%)	6/16 (37.5%)
Citrobacter freundii complex	8/12 (66.7%)	2/5 (40%)
Staphylococcus saprophyticus	9/15 (60%)	11/14 (78.6%)
Enterococcus faecalis	8/14 (57.1%)	2/7 (28.6%)

- The efficacy of Blujepa for suspected uncomplicated urogenital gonorrhea due to *Neisseria gonorrhoeae* was assessed in an open-label, randomized, active-controlled, multicenter, multinational study.
  - Patients were randomized to receive either Blujepa or a combination of a single intramuscular (IM) 500mg dose of ceftriaxone and single 1g oral dose of azithromycin.
  - Patients were eligible for enrollment if they were ≥12 years of age and >45kg.
  - The microbiological intent-to-treat (micro-ITT) population, which included patients who had urogenital *N. gonorrhoeae* isolated at baseline and who were not infected with a strain that was non susceptible to ceftriaxone at baseline, included 406 patients.
  - The demographic and baseline characteristics in the micro-ITT population were comparable between treatment groups.

- In total, 92% were male, 74% were White, the mean age of included patients was 33 years (range 17 to 64), and the mean weight was 76kg.

- The primary efficacy endpoint was microbiological success as determined by confirmed bacterial eradication of *N. gonorrhoeae* at the urogenital body site at the test of cure (TOC) visit (day 4 to 8) without receipt of other systemic antimicrobials and was assessed in the micro-ITT population.
  - Results demonstrated non-inferiority of Blujepa to the combination of ceftriaxone and azithromycin.
  - Results are presented in the table below, which was adapted from the prescribing information.

Table 5. Efficacy results

	Blujepa n/N (%)	Ceftriaxone & Azithromycin n/N (%)	Treatment Difference
Microbiological success	187/202 (92.6%)	186/204 (91.2%)	-0.1
Microbiological failure	15/202 (7.4%)	18/204 (8.8%)	
Bacterial persistence by culture	0	0	
Unable to determine	15/202 (7.4%)	18/204 (8.8%)	

Clinical guidelines

- There are currently no published guidelines addressing the use of Blujepa for the treatment of uUTI or uncomplicated urogenital gonorrhea as the guidelines were published prior to FDA approval.
- Infectious Diseases Society of American (IDSA) notes that updated uUTI guidelines are in development. It is unknown whether Blujepa will be included in these guidelines (*IDSA website*).
- **IDSA 2024 Guidance on the Treatment of Antimicrobial-Resistant Gram-Negative Infections** (*Tamma et al 2024*)
  - Preferred antibiotics for the treatment of uncomplicated cystitis caused by extended-spectrum β-lactamase-producing Enterobacterales (ESBL-E) include nitrofurantoin and trimethoprim-sulfamethoxazole (TMP/SMX).
  - Alternatives include ciprofloxacin, levofloxacin, and carbapenems; although effective, use is discouraged when nitrofurantoin or TMP/SMX are active.
  - An aminoglycoside (as a single dose) and oral fosfomycin (for *E. coli* only) are also treatment options for uUTI caused by ESBL-E.
- **International clinical practice guidelines for the treatment of acute uncomplicated cystitis and pyelonephritis in women: A 2010 update by the IDSA and the European Society for Microbiology and Infectious Diseases (ESMID).** (*Gupta et al 2011*).
  - These guidelines are limited to the treatment of UTI in premenopausal, nonpregnant women with no known urological abnormalities or comorbidities.
  - In women with acute uncomplicated cystitis (eg, no fever, flank pain, or other suspicion for pyelonephritis), antimicrobials should be considered based on (1) availability, (2) allergy history, and (3) tolerance.
  - Guideline-recommended first-line antibiotics include nitrofurantoin, trimethoprim-sulfamethoxazole (TMP/SMX) double strength (DS), fosfomycin, and pivmecillinam.
- **World Health Organization (WHO) Guidelines for the Treatment of *Neisseria gonorrhoeae*** (*WHO 2016*).
  - Regarding genital and anorectal gonococcal infections:

- The WHO sexually transmitted infection (STI) guidelines recommends that local resistance data should determine the decision on which therapy to utilize. When data are not available, the guidelines suggests dual therapy rather than single therapy.
- The guidelines suggests the following treatment options:
  - Dual therapy (one of the following):
    - Ceftriaxone 250mg IM as a single dose PLUS azithromycin 1g PO as a single dose.
    - Cefixime 400mg PO as a single dose PLUS azithromycin 1g PO as a single dose.
  - Single therapy (one of the following, based on recent local resistance data confirming susceptibility to the antimicrobial):
    - Ceftriaxone 250mg IM as a single dose.
    - Cefixime 400mg PO as a single dose.
    - Spectinomycin 2g IM as a single dose.
  - The authors note that due to emerging resistance data for gonococcal infections and reduced efficacy of some medications, good practice ensures that the choice of treatment depends on reliable local data on antimicrobial susceptibility. Alternative single-medicine treatments, such as gentamicin or kanamycin, have not been suggested because of lack of surveillance date. Guidance for surveillance of antimicrobial resistance to *N. gonorrhoeae* is available from WHO.

Safety summary

- **Contraindications:**
  - In patients with a history of severe hypersensitivity to Blujepa.

- **Box Warning:** None.

- **Warnings and precautions:**
  - A dose and concentration-dependent prolongation of the QTc interval has been observed with Blujepa.
    - Avoid Blujepa in patients with a history of QTc interval prolongation or those with relevant preexisting cardiac disease, patients taking antiarrhythmic agents, or other medications that may potentially prolong the QTc interval.
    - Avoid concomitant administration of Blujepa with strong CYP3A4 inhibitors, in patients with severe hepatic impairment, or in patients with severe renal impairment.
    - In addition, avoid Blujepa in uncomplicated urogenital gonorrhea patients who also have any of the following risk factors for increased gepotidacin exposure:
      - Concomitant use of moderate CYP3A4 inhibitors.
      - Two or more of the following risk factors:
        - Body weight between 45kg and 60kg.
        - Moderate renal impairment.
        - Moderate hepatic impairment.
    - If administration of Blujepa cannot be avoided in these patients, monitor and correct serum electrolyte abnormalities and collect an ECG prior to administration and during treatment, as clinically indicated.
  - Blujepa is a reversible acetylcholinesterase inhibitor in in vitro laboratory studies. Adverse reactions including dysarthria, syncope, presyncope, muscle spasms, diarrhea, nausea, vomiting, abdominal pain, hypersalivation, and hyperhidrosis which are potentially attributed to acetylcholinesterase inhibition, have been observed in clinical trials. Increased cholinergic effects can be associated with severe adverse reactions including atrioventricular block, bradycardia, bronchospasm, and seizures/convulsions. Monitor patients with medical conditions that may be exacerbated by acetylcholinesterase inhibition.

- Blujepa may exaggerate the neuromuscular effects of succinylcholine-type muscle relaxation during anesthesia. It may exaggerate the effects of other acetylcholinesterase inhibitors. Monitor for exaggerated neuromuscular blockade or excessive cholinergic effects.
  - As Blujepa may antagonize the effects of systemic anticholinergic medications or non-depolarizing neuromuscular blocking agents, monitor patients if Blujepa is concomitantly administered with these medications.
- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving Blujepa. Before therapy with Blujepa is started, carefully inquire about previous hypersensitivity reactions to Blujepa. If an allergic reaction to Blujepa occurs, discontinue the drug and start appropriate supportive measures.
- *Clostridioides difficile* (*C. difficile*) infection (CDI) has been reported for nearly all systemic antibacterial agents, including Blujepa, and may range in severity from mild diarrhea to fatal colitis. CDI must be considered in all patients who present with diarrhea following antibacterial drug use, Careful medical history is necessary as CDI has been reported to occur over 2 months after the administration of antibacterial agents.
  - If CDI is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial drug treatment of *C. difficile*, and surgical evaluation should be started as clinically indicated.
- Prescribing Blujepa in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

- **Common adverse drug reactions**: Listed % incidence for adverse drug reactions= reported % incidence for drug (Blujepa) minus reported % incidence for nitrofurantoin. Please note that an incidence of 0% means the incidence was the same as or less than comparator.
  - The most frequently reported adverse events included diarrhea (13%), nausea (5%), abdominal pain (2%), flatulence (<3%), headache (0%), soft feces (<2%), dizziness (1%), vomiting (<2%), and vulvovaginal candidiasis (0%).

- **Drug interactions:**
  - Avoid concomitant administration of Blujepa with strong inhibitors of CYP3A4.
  - Avoid concomitant administration of Blujepa with moderate CYP3A4 inhibitors in patients with uncomplicated urogenital gonorrhea.
  - Due to a decrease in gepotidacin exposures, avoid concomitant administration of Blujepa with CYP3A4 inducers as follows:
    - uUTIs: Avoid concomitant use of Blujepa with strong CYP3A4 inducers.
    - Uncomplicated urogenital gonorrhea: Avoid concomitant use of Blujepa with strong and moderate CYP3A4 inducers.
  - Avoid concomitant administration of Blujepa with drugs that are extensively metabolized by CYP3A4 where minimal concentration changes may lead to serious adverse reactions.
  - Due to an increase in digoxin exposures, consider monitoring digoxin serum concentrations, as appropriate, with concomitant administration of Blujepa.
  - As gepotidacin is an acetylcholinesterase inhibitor, there is potential for an exaggerated effect of concomitantly administered succinylcholine-type neuromuscular blocking agents resulting in a delay in recovery of neuromuscular function. Blujepa may augment the effect of other acetylcholinesterase inhibitors. Monitor for exaggerated neuromuscular blockade or excessive cholinergic effects.
  - There is potential for an antagonistic effect with systemic anticholinergic medications or non-depolarizing neuromuscular blocking agents. Consider the potential for this interaction if Blujepa is administered concomitantly with anticholinergic medications.

- Due to the increased risk of QTc prolongation, avoid concomitant administration of Blujepa with other medications that have the potential to prolong the QTc interval.

- **Special populations:**
  - There is no pregnancy category for this medication; however, the risk summary indicates that there are no available data on the use of Blujepa in pregnant women to assess for a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes.
    - A pregnancy exposure registry will be established to monitor pregnancy outcomes in women exposed to Blujepa during pregnancy. Pregnant women exposed to Blujepa, and healthcare providers are encouraged to contact GlaxoSmithKline at 1-888-825-5249.
  - The safety and efficacy of use in the pediatric population less than 12 years of age or weighing less than 40kg have not been established with the uUTI indication.
  - The safety and efficacy of use in the pediatric population less than 12 years of age or weighing less than 45kg have not been established with the uncomplicated urogenital gonorrhea indication

Conclusion

- An uncomplicated urinary tract infection (uUTI) is an infection of the bladder (cystitis, lower urinary tract) in females who are not pregnant and who do not have functional or anatomical abnormalities in the urinary tract or other comorbidities that may lead to a more challenging infection to treat (*Gupta 2026, Orrange et al 2025*).
- A common sexually transmitted infection (STI) that is treatable includes gonorrhea (*CDC 2025*). However, globally, it is a major cause of morbidity in sexually active individuals (*Ghanem 2026*).
- Blujepa is indicated:
  - In female adult and pediatric patients 12 years of age and older weighing at least 40kg for the treatment of uUTI caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii* complex, *Staphylococcus saprophyticus*, and *Enterococcus faecalis*.
  - In adult and pediatric patients 12 years of age and older weighing at least 45kg who have limited or no alternative options for the treatment of uncomplicated urogenital gonorrhea caused by susceptible strains of Neisseria gonorrhoeae. Approval of this indication is based on limited clinical safety data for Blujepa.
  - To reduce the development of drug-resistant bacteria and maintain the effectiveness of Blujepa and other antibacterial drugs, Blujepa should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
- A dose and concentration-dependent prolongation of the QTc interval has been observed with Blujepa.
  - Avoid Blujepa in patients with a history of QTc interval prolongation or those with relevant preexisting cardiac disease, patients taking antiarrhythmic agents, or other medications that may potentially prolong the QTc interval.
- The efficacy of Blujepa was assessed in 2 double-blind, double-dummy, non-inferiority trials that compared Blujepa to nitrofurantoin in female patients with uUTI.
  - Patients entered the trials with at least 2 symptoms consistent with uUTI.
  - Efficacy was assessed as a composite of clinical cure and microbiological response at the TOC visit in the micro-ITTS population.
    - Both trials demonstrated non-inferiority of Blujepa to nitrofurantoin for the composite response.
- The efficacy of Blujepa in patients with suspected uncomplicated urogenital gonorrhea was assessed in an open-label, active-controlled, multicenter study that compared Blujepa with a combination of ceftriaxone IM and azithromycin PO.

- The primary efficacy endpoint was microbiological success as determined by confirmed bacterial eradication of *N. gonorrhoeae* at the urogenital body site at the TOC visit without receipt of other systemic antimicrobials and was assessed in the micro-ITT population.
  - Results demonstrated non-inferiority of Blujepa to the combination of ceftriaxone and azithromycin.
- Guidelines for either indication do not currently include Blujepa, as they were published prior to Blujepa being FDA approved. Nitrofurantoin is listed as a first-line treatment for uUTI.

- There is no evidence to suggest that Blujepa is safer or more effective than other currently preferred, more cost-effective medications. It is therefore recommended that Blujepa remain non-preferred and require prior authorization and be available to those who are unable to tolerate or who have failed preferred medications.

- **PDL Placement:**
  - ☐ Preferred
  - ☒ Non-Preferred

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