Indication

BLUJEPA is indicated for the treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) with uncomplicated urinary tract infections (uUTI) caused by susceptible microorganisms.

Usage to Reduce Development of Drug-Resistant Bacteria
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 bacteria.

UTI=urinary tract infection.

BLUJEPA: an effective, first-in-class antibiotic for patients with uncomplicated UTIs, with proven efficacy and a demonstrated safety profile[1,2]

See clinical trial data inside.

Important Safety Information

CONTRAINDICATIONS
BLUJEPA is contraindicated in patients with a history of severe hypersensitivity to BLUJEPA.

WARNINGS AND PRECAUTIONS
QTc Prolongation
- A dose and concentration-dependent prolongation of the QTc interval has been observed with BLUJEPA. Avoid use of BLUJEPA in patients with a history of QTc prolongation or with relevant pre-existing cardiac disease, patients taking antiarrhythmic agents, or in patients receiving drugs that prolong the QTc interval.
- Due to an increase in gepotidacin exposure and the risk of QTc interval prolongation, avoid use of BLUJEPA in patients who have any of the following risk factors:
  - Concomitant use of strong CYP3A4 inhibitors
  - Severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min)
  - Severe hepatic impairment (Child-Pugh Class C)

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for BLUJEPA.

BLUJEPA (gepotidacin) 750 mg tablets

Women at risk of uUTI treatment failure may need another option when treated empirically

A retrospective study of 376,004 US female patients who were empirically prescribed oral antibiotics for uncomplicated urinary tract infections (uUTIs) found that 17% experienced treatment failure (defined as a uUTI requiring additional clinical intervention within 28 days of initial treatment, eg, a second antibiotic or an emergency department visit or inpatient stay with a new primary diagnosis of uUTI).[3]

Consider these patient characteristics, identified in a recent study, that increased risk of treatment failure[3]:

History of recurrent uUTIs

Age 50 years and older

Previous antibiotic use within the past 12 months

Treatment failure rates are also higher among patients with antibiotic-resistant infections[4]

Learn more about risk factors for uUTI treatment failure.

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

Acetylcholinesterase Inhibition

- Dysarthria and other adverse reactions potentially attributed to acetylcholinesterase inhibition have been reported with BLUJEPA, a reversible acetylcholinesterase inhibitor. 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 and patients receiving succinylcholine-type or non-depolarizing neuromuscular blocking agents, or systemic anticholinergic medications.

Hypersensitivity Reactions

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving BLUJEPA. If an allergic reaction to BLUJEPA occurs, discontinue the drug and institute appropriate supportive measures.

***Clostridioides difficile* Infection**

- *Clostridioides difficile* infection (CDI) has been reported with nearly all systemic antibacterial agents, including BLUJEPA. Evaluate patients who develop diarrhea.

ADVERSE REACTIONS

- The most common adverse reactions occurring in ≥1% of patients are diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candidiasis.

DRUG INTERACTIONS

- CYP3A4 Inhibitors: Avoid coadministration of BLUJEPA with strong CYP3A4 inhibitors due to increased gepotidacin exposure.

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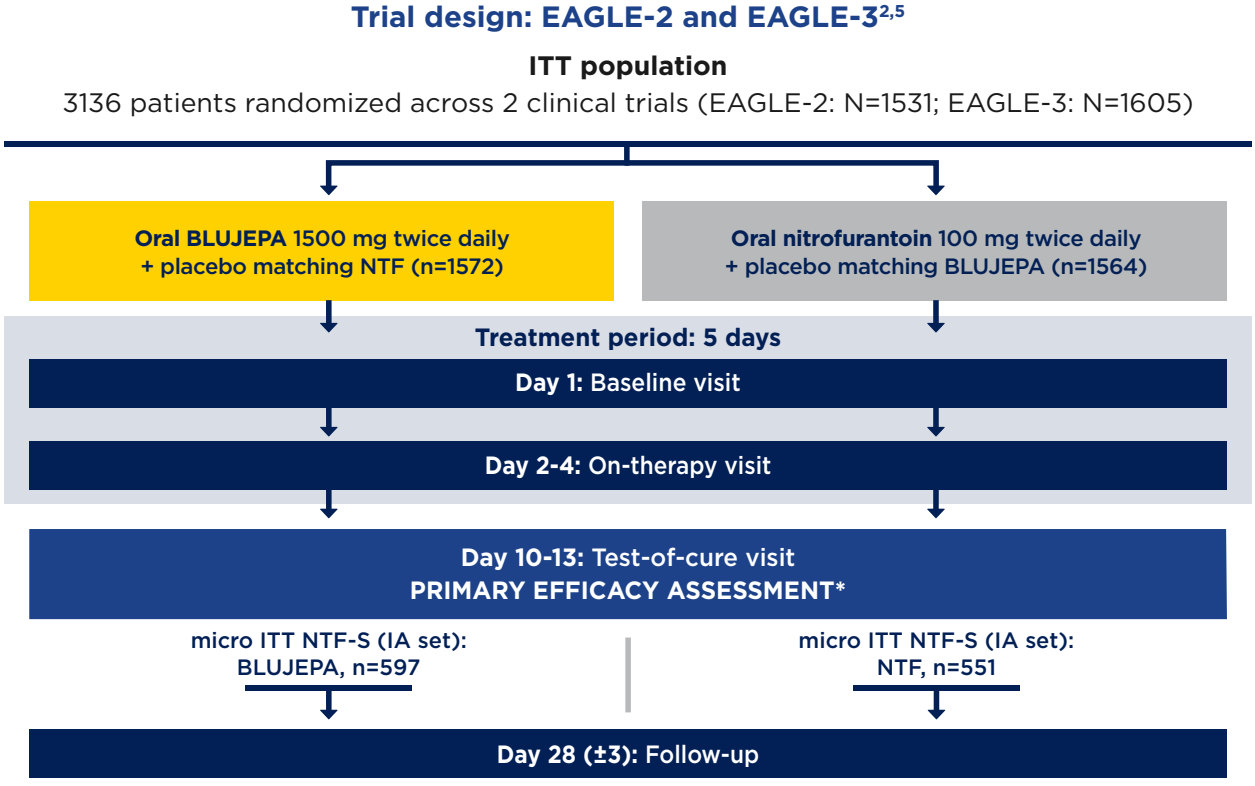
BLUJEPA (gepotidacin) 750 mg tablets

BLUJEPA was studied in 2 noninferiority clinical trials vs nitrofurantoin (NTF), the current standard of care[1,2]

EAGLE-2 and EAGLE-3 were phase 3, randomized, double-blind, double-dummy, noninferiority trials comparing BLUJEPA with NTF for the treatment of uUTIs.[2]

Trial design: EAGLE-2 and EAGLE-3[2,5]



- Patients were nonpregnant; weighed ≥40 kg; had 2 or more symptoms of dysuria, frequency, urgency, or lower abdominal pain (with an onset <96 hours of study entry); and had nitrite or pyuria (presence of 3+/large leukocyte esterase) on a urine dipstick test from a pre-treatment clean-catch midstream urine sample[2]

*Both trials stopped early on the basis of a pre-specified interim analysis for efficacy.[2]

IA=interim analysis; ITT=intent-to-treat; micro=microbiological; NTF=nitrofurantoin; NTF-S=nitrofurantoin-susceptible; uUTI=uncomplicated urinary tract infection.

Important Safety Information (cont'd)

DRUG INTERACTIONS

- CYP3A4 Inducers: Avoid coadministration of BLUJEPA with strong CYP3A4 inducers due to decreased gepotidacin exposure.
- CYP3A4 Substrates: Avoid coadministration of BLUJEPA with drugs that are extensively metabolized by CYP3A4 where minimal concentration changes may lead to serious adverse reactions.
- Digoxin: Due to an increase in digoxin exposures, consider monitoring digoxin serum concentration, as appropriate, with concomitant administration of BLUJEPA.

USE IN SPECIFIC POPULATIONS

- Renal Impairment: Avoid use of BLUJEPA in patients with severe renal impairment with eGFR <30 mL/min, including those receiving dialysis.
- Hepatic Impairment: Avoid use of BLUJEPA in patients with severe hepatic impairment (Child-Pugh Class C).

Therapeutic response evaluation[2]

EAGLE-2 and EAGLE-3 were designed in accordance with current FDA guidance for uUTI trials, which includes stringent criteria for clinical trial design. The primary endpoint, therapeutic response, could be classified as either success or failure.[2,6]

Efficacy was based on therapeutic success[2]
Therapeutic success required both clinical success and microbiological success, assessed at the test-of-cure visit (day 10-13).[2]

THERAPEUTIC SUCCESS required both[2]:

Clinical success

Complete resolution of the following baseline signs and symptoms of acute cystitis without additional antibiotic use for uUTI:

- Dysuria
- Urgency
- Frequency
- Lower abdominal pain

***AND* No new signs/symptoms**

Microbiological success

Eradication of qualifying uropathogens present at baseline (reduction from ≥10^5 CFU/mL to <10^3 CFU/mL) without additional antibiotic use for uUTI

Therapeutic failure was defined as any combination of microbiological failure, clinical failure, or missing data.[2]

CFU=colony-forming units; uUTI=uncomplicated urinary tract infection.

Important Safety Information

CONTRAINDICATIONS
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WARNINGS AND PRECAUTIONS

QTc Prolongation

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  - Concomitant use of strong CYP3A4 inhibitors
  - Severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min)
  - Severe hepatic impairment (Child-Pugh Class C)

Acetylcholinesterase Inhibition

- Dysarthria and other adverse reactions potentially attributed to acetylcholinesterase inhibition have been reported with BLUJEPA, a reversible acetylcholinesterase inhibitor. 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 and patients receiving succinylcholine-type or non-depolarizing neuromuscular blocking agents, or systemic anticholinergic medications.

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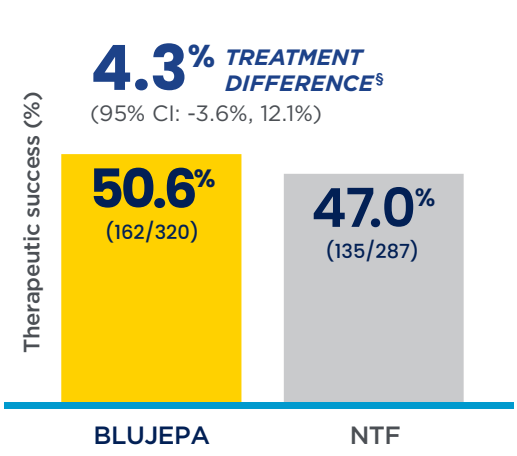
BLUJEPA (gepotidacin) 750 mg tablets

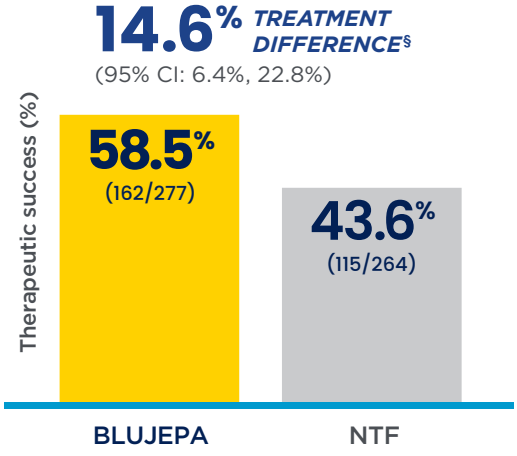
BLUJEPA achieved noninferiority* to nitrofurantoin (NTF) in both trials[2]

BLUJEPA also achieved superiority† in EAGLE-3[2]

EAGLE-2: Therapeutic success[2‡]



EAGLE-3: Therapeutic success[2‡]



Predefined secondary endpoints[2]	EAGLE-2			EAGLE-3		
	BLUJEPA	NTF	Adjusted difference (95% CI)	BLUJEPA	NTF	Adjusted difference (95% CI)
Microbiological success[2]	72.5%	67.6%	5.2% (-2.1-12.5)	72.2%	57.2%	15% (7.2-22.9)
Clinical success[2]	65.6%	65.2%	1.2% (-6.3-8.7)	67.9%	63.3%	4.4% (-3.5-12.3)

Results are descriptive only. No formal hypothesis testing was performed.

*Noninferiority at IA was assessed with the Z statistic; in both trials, the observed value exceeded the boundary (EAGLE-2: 3.5554 vs 2.065; EAGLE-3: 5.8838 vs 2.098), confirming noninferiority to NTF.[2]

†Having achieved noninferiority, superiority was tested and declared if the observed *P* value was less than the boundary. EAGLE-2: 0.1445 vs 0.019 (no superiority); EAGLE-3: 0.0003 vs 0.018 (superiority achieved).[2]

‡Therapeutic response was assessed as success or failure; the results presented are for therapeutic success, which required both clinical success (ie, complete symptom resolution) and microbiological success (ie, reduction of qualifying uropathogens from ≥10^5 CFU/mL at baseline to <10^3 CFU/mL) without additional antibiotic use for uncomplicated UTI at test-of cure.[2]

§Treatment difference (BLUJEPA – NTF) calculated using Miettinen-Nurminen Summary Score method adjusted for age group and recurrent/nonrecurrent infection status combinations.[2]

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving BLUJEPA. If an allergic reaction to BLUJEPA occurs, discontinue the drug and institute appropriate supportive measures.

***Clostridioides difficile* Infection**

- *Clostridioides difficile* infection (CDI) has been reported with nearly all systemic antibacterial agents, including BLUJEPA. Evaluate patients who develop diarrhea.

ADVERSE REACTIONS

- The most common adverse reactions occurring in ≥1% of patients are diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candidiasis.

DRUG INTERACTIONS

- CYP3A4 Inhibitors: Avoid coadministration of BLUJEPA with strong CYP3A4 inhibitors due to increased gepotidacin exposure.

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BLUJEPA (gepotidacin) 750 mg tablets

EAGLE-2 and EAGLE-3 pooled safety results[1]

Adverse reactions occurring in ≥1% of patients treated with BLUJEPA (pooled data, safety population)[1]

Adverse Reaction	BLUJEPA (N=1570)	NTF (N=1558)
Diarrhea	**258** (16%)	**51** (3%)
Nausea	**146** (9%)	**64** (4%)
Abdominal pain*	**60** (4%)	**34** (2%)
Flatulence	**43** (3%)	**8** (<1%)
Headache	**38** (2%)	**40** (3%)
Soft feces	**37** (2%)	**8** (<1%)
Dizziness	**29** (2%)	**19** (1%)
Vomiting	**28** (2%)	**10** (<1%)
Vulvovaginal candidiasis	**20** (1%)	**18** (1%)

Across both trials, diarrhea was reported in 16% (258/1570) of patients receiving BLUJEPA; 11% were mild, 5% moderate, and <1% severe. The diarrhea started within the first 2 days of treatment for the majority of patients, and the median duration of diarrhea was 4 days.[1]

- Serious adverse reactions occurred in <1% (1/1570) of patients treated with BLUJEPA and <1% (1/1558) of patients treated with nitrofurantoin. The serious adverse reaction reported with BLUJEPA was dysarthria[1]
- Treatment discontinuation due to adverse reactions occurred in 5% (79/1570) of patients treated with BLUJEPA and 2% (30/1558) of patients treated with NTF[1]
- Adverse reactions occurring in >1% of patients and leading to treatment discontinuation of BLUJEPA therapy included diarrhea (3%) and nausea (1%)[1]

*Abdominal pain includes abdominal pain, abdominal pain upper, abdominal pain lower, abdominal pain tenderness, abdominal discomfort, and gastrointestinal pain.[1]

NTF=nitrofurantoin.

Important Safety Information (cont'd)

DRUG INTERACTIONS

- CYP3A4 Inducers: Avoid coadministration of BLUJEPA with strong CYP3A4 inducers due to decreased gepotidacin exposure.
- CYP3A4 Substrates: Avoid coadministration of BLUJEPA with drugs that are extensively metabolized by CYP3A4 where minimal concentration changes may lead to serious adverse reactions.
- Digoxin: Due to an increase in digoxin exposures, consider monitoring digoxin serum concentration, as appropriate, with concomitant administration of BLUJEPA.

USE IN SPECIFIC POPULATIONS

- Renal Impairment: Avoid use of BLUJEPA in patients with severe renal impairment with eGFR <30 mL/min, including those receiving dialysis.
- Hepatic Impairment: Avoid use of BLUJEPA in patients with severe hepatic impairment (Child-Pugh Class C).

Important Safety Information

CONTRAINDICATIONS

BLUJEPA is contraindicated in patients with a history of severe hypersensitivity to BLUJEPA.

Symptom Improvement Study

Evaluation of symptom improvement and safety of BLUJEPA in uUTI treatment: results from a phase 3b, open-label, single-arm, US study (N=97)[7]*

Assessment of uUTI Clinical Symptom Score (CSS): calculated by rating uUTI symptoms—dysuria, frequency, urgency, and lower abdominal pain—on a 0-3 scale (none to severe) and summing for a total CSS (0-12).[7]*

- **Symptom improvement:** ≥1-point decrease from baseline in CSS
- **Symptom resolution:** no symptoms (CSS of 0)

Percentages of clinical symptom improvement or resolution:

- **Primary endpoint:** 54.4% of clinically evaluable† patients (49/90) at 24 (±4) hours after their first BLUJEPA dose[7]
- **Secondary endpoint:** ~80% of clinically evaluable† patients (71/89) at 48 (±4) hours after their first BLUJEPA dose[7]

Results are descriptive only. No formal hypothesis test. Data are from an open-label study that assessed clinical improvement via telephone visits.[7]

Adverse events (AEs) that occurred in ≥2% of patients were[7]:

- Diarrhea (16%)
- Flatulence (6%)
- Dizziness (5%)
- Abdominal pain (4%)
- Headache (3%)
- Abdominal discomfort (2%)
- Nausea (2%)

AEs were mild or moderate in 93% (25/27) of patients; 2 patients experienced severe drug-related diarrhea.
No patients experienced *C. difficile*-associated diarrhea.
No serious AEs occurred.[7]

*Study enrolled females (≥12 years, ≥40 kg) presenting within 96 hours of uUTI onset and having at least 2 symptoms (dysuria, frequency, urgency, or lower abdominal pain) and dipstick evidence of nitrite or pyuria (≥3+/large leukocyte esterase) on a pre-treatment midstream urine sample.[7]

†Clinically evaluable patients must have taken 2 doses of BLUJEPA at 24 (±4) hours and at least 80% of planned doses at 48 (±4) hours, without using other systemic antimicrobials before CSS assessment conducted via telephone.[7]

C. difficile=*Clostridioides difficile*; uUTI=uncomplicated urinary tract infection.

Important Safety Information

WARNINGS AND PRECAUTIONS

QTc Prolongation

- A dose and concentration-dependent prolongation of the QTc interval has been observed with BLUJEPA. Avoid use of BLUJEPA in patients with a history of QTc prolongation or with relevant pre-existing cardiac disease, patients taking antiarrhythmic agents, or in patients receiving drugs that prolong the QTc interval.
- Due to an increase in gepotidacin exposure and the risk of QTc interval prolongation, avoid use of BLUJEPA in patients who have any of the following risk factors:
  - Concomitant use of strong CYP3A4 inhibitors
  - Severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min)
  - Severe hepatic impairment (Child-Pugh Class C)

Acetylcholinesterase Inhibition

- Dysarthria and other adverse reactions potentially attributed to acetylcholinesterase inhibition have been reported with BLUJEPA, a reversible acetylcholinesterase inhibitor. 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 and patients receiving succinylcholine-type or non-depolarizing neuromuscular blocking agents, or systemic anticholinergic medications.

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BLUJEPA (gepotidacin) 750 mg tablets

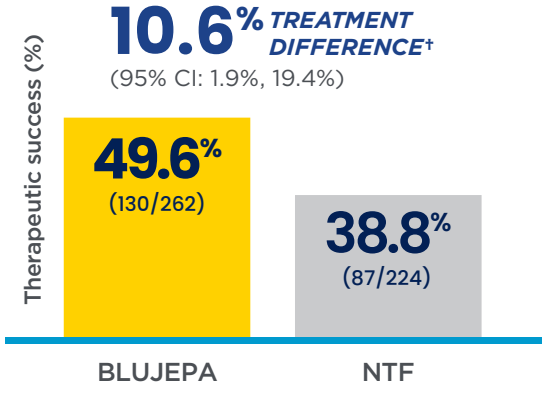
Choose BLUJEPA for appropriate patients with uncomplicated UTI who may be at risk of treatment failure

See pages 3 and 4 for trial design details, and pages 5 and 6 for primary endpoint and safety profile data.

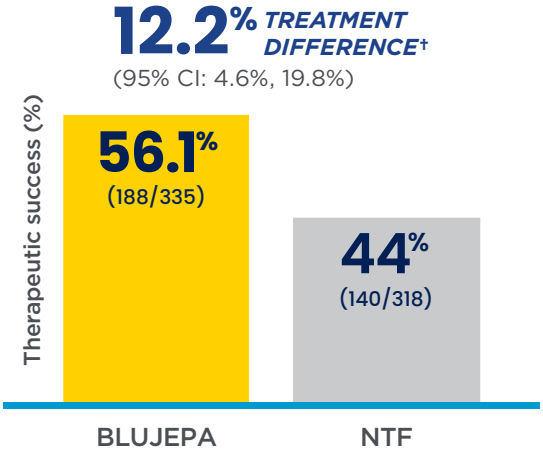
Subgroup analyses from EAGLE-2 and EAGLE-3: In patients considered at risk for resistant uropathogens—those with a **history of recurrent uUTIs*** and **>50 years old**—therapeutic response was assessed at the test-of-cure visit in the microbiological ITT population with NTF-susceptible isolates (complete data set).[2,5]

Results are descriptive only. No formal hypothesis testing was performed.

Therapeutic response in female patients with a history of recurrent uUTIs (pooled data)[7]



Therapeutic response in female patients >50 years old (pooled data)[7]



*History of recurrent uUTIs was defined as at least 1 previous patient-reported episode within 3 months before study entry, at least 2 previous episodes within 6 months before study entry, or at least 3 previous episodes within 12 months before study entry.[2]

†Treatment difference (BLUJEPA – NTF) calculated using Miettinen-Nurminen Summary Score method adjusted for age group and recurrent/nonrecurrent infection status combinations.[2]

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving BLUJEPA. If an allergic reaction to BLUJEPA occurs, discontinue the drug and institute appropriate supportive measures.

***Clostridioides difficile* Infection**

- *Clostridioides difficile* infection (CDI) has been reported with nearly all systemic antibacterial agents, including BLUJEPA. Evaluate patients who develop diarrhea.

ADVERSE REACTIONS

- The most common adverse reactions occurring in ≥1% of patients are diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candidiasis.

DRUG INTERACTIONS

- CYP3A4 Inhibitors: Avoid coadministration of BLUJEPA with strong CYP3A4 inhibitors due to increased gepotidacin exposure.
- CYP3A4 Inducers: Avoid coadministration of BLUJEPA with strong CYP3A4 inducers due to decreased gepotidacin exposure.
- CYP3A4 Substrates: Avoid coadministration of BLUJEPA with drugs that are extensively metabolized by CYP3A4 where minimal concentration changes may lead to serious adverse reactions.

Therapeutic response in patients with **antibiotic-resistant (including multidrug-resistant)** ***E. coli*** (pooled data)[7]

Results are descriptive only. No formal hypothesis testing was performed.

	Therapeutic success		
	BLUJEPA (n=628)	**NTF** (n=567)	**Treatment difference** (95% CI)
*E. coli**	**55.1%** (312/556)	**45.0%** (234/520)	**10.2%** (4.3%, 16.1%)
ESBL+	**53.6%** (45/84)	**38.5%** (25/65)	**14.8%** (-0.7%, 30.3%)
FQ-resistant	**48.4%** (78/161)	**39.1%** (50/128)	**9.1%** (-2.3%, 20.4%)
TMP-SMX-resistant	**54.4%** (87/160)	**43.9%** (58/132)	**10.2%** (-1.2%, 21.5%)
Multidrug-resistant†	**51.9%** (83/160)	**41.7%** (53/127)	**9.9%** (-1.6%, 21.3%)

*Patients with >1 uropathogen of the same species were counted once.[2]

†Multidrug resistance was defined as a uropathogen being resistant to ≥3 relevant antibacterial classes.[5]

E. coli=Escherichia coli; ESBL+=extended-spectrum beta-lactamase positive; FQ=fluoroquinolone; TMP-SMX=trimethoprim-sulfamethoxazole; uUTI=uncomplicated urinary tract infection.

Choose BLUJEPA for appropriate patients who have a history of recurrent uUTIs, are >50 years old, or have antibiotic-resistant *E. coli*.

Important Safety Information (cont'd)

DRUG INTERACTIONS

- Digoxin: Due to an increase in digoxin exposures, consider monitoring digoxin serum concentration, as appropriate, with concomitant administration of BLUJEPA.

USE IN SPECIFIC POPULATIONS

- Renal Impairment: Avoid use of BLUJEPA in patients with severe renal impairment with eGFR <30 mL/min, including those receiving dialysis.
- Hepatic Impairment: Avoid use of BLUJEPA in patients with severe hepatic impairment (Child-Pugh Class C).

Important Safety Information

CONTRAINDICATIONS

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WARNINGS AND PRECAUTIONS

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- Due to an increase in gepotidacin exposure and the risk of QTc interval prolongation, avoid use of BLUJEPA in patients who have any of the following risk factors:
  - Concomitant use of strong CYP3A4 inhibitors
  - Severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min)
  - Severe hepatic impairment (Child-Pugh Class C)

Do you have patients with uUTIs like...

Jill Age 38

Jill has a uUTI and is at risk for empiric treatment failure due to her history of recurrent uUTIs.[3]

Medical history

- Has had 3 UTIs in the past year
- Fully adherent to her antibiotic treatment regimens
- Otherwise healthy

"I'm a teacher, and it's embarrassing to excuse myself every few minutes to go to the bathroom. I'm getting really frustrated by my UTIs."

Kayla Age 58

Kayla has a uUTI. She is over 50 and has recently been treated with an antibiotic; these are factors that put her at risk for failing empiric uUTI treatment.[3]

Medical history

- Treated for a uUTI ~12 months ago and completed a full course of therapy
- Received antibiotic for an unrelated condition 4 months ago and was fully adherent to her antibiotic treatment
- Otherwise healthy

"I'm working toward an early retirement so I can spend more time with my grandchildren. I want to get rid of this UTI and get on with life."

Not actual patients. For illustration purposes only.

UTI=urinary tract infection; uUTI=uncomplicated urinary tract infection.

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

Acetylcholinesterase Inhibition

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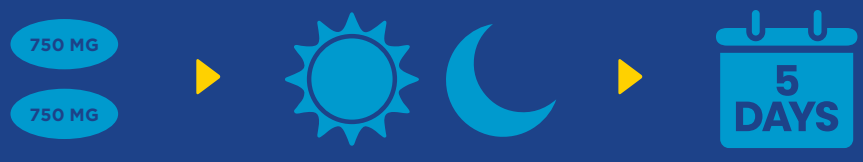
***Clostridioides difficile* Infection**

- *Clostridioides difficile* infection (CDI) has been reported with nearly all systemic antibacterial agents, including BLUJEPA. Evaluate patients who develop diarrhea.

BLUJEPA is taken as two 750-mg tablets (1500 mg total), twice daily, for 5 days[1]



2 TABLETS **TWICE DAILY** **FOR 5 DAYS**

Approximately 12 hours apart, after meals

No dose adjustments are required for patients with mild-to-moderate renal impairment (estimated glomerular filtration rate [eGFR] of 30-89 mL/min)[1]

- Avoid use of BLUJEPA in patients with severe renal impairment or kidney failure (eGFR <30 mL/min), including those receiving dialysis, due to increased exposure to gepotidacin and the risk of QTc prolongation

No dose adjustments are required for patients with mild or moderate hepatic impairment (Child-Pugh Class A or B)[1]

- Avoid use of BLUJEPA in patients with severe hepatic impairment (Child-Pugh Class C) due to increased exposure to gepotidacin and the risk of QTc prolongation

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Tablets should be taken after a meal to reduce the possibility of gastrointestinal intolerance[1]

If a dose of BLUJEPA is missed, it should be taken as soon as possible. Double doses should not be taken to make up for a missed dose[1]

Important Safety Information (cont'd)

ADVERSE REACTIONS

- The most common adverse reactions occurring in ≥1% of patients are diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candidiasis.

DRUG INTERACTIONS

- CYP3A4 Inhibitors: Avoid coadministration of BLUJEPA with strong CYP3A4 inhibitors due to increased gepotidacin exposure.
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BLUJEPA (gepotidacin) 750 mg tablets

Dedicated to helping your patients get the treatment you prescribe

Learn about BLUJEPA coverage for your patients with our Coverage Finder Tool

When you decide that BLUJEPA is an appropriate treatment for a patient, insurance coverage is an important consideration.

The Coverage Finder Tool lets you search for insurance coverage details by region or payer.

Savings available for your eligible, commercially insured BLUJEPA patients

The **BLUJEPA savings coupon** can help patients with their out-of-pocket cost.

Subject to eligibility. Restrictions apply.

See the coupon, eligibility requirements, and terms and conditions.

Visit BlujepaHCP.com to learn more about BLUJEPA coverage and the savings coupon.

Important Safety Information (cont'd)

USE IN SPECIFIC POPULATIONS

- Renal Impairment: Avoid use of BLUJEPA in patients with severe renal impairment with eGFR <30 mL/min, including those receiving dialysis.
- Hepatic Impairment: Avoid use of BLUJEPA in patients with severe hepatic impairment (Child-Pugh Class C).

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QTc Prolongation

- A dose and concentration-dependent prolongation of the QTc interval has been observed with BLUJEPA. Avoid use of BLUJEPA in patients with a history of QTc prolongation or with relevant pre-existing cardiac disease, patients taking antiarrhythmic agents, or in patients receiving drugs that prolong the QTc interval.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for BLUJEPA.

BLUJEPA (gepotidacin) 750 mg tablets

Indication

BLUJEPA is indicated for the treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) with uncomplicated urinary tract infections (uUTI) caused by susceptible microorganisms.

Usage to Reduce Development of Drug-Resistant Bacteria
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 bacteria.

Choose BLUJEPA with confidence for your appropriate patients with uUTIs

Complete symptom resolution and uropathogen eradication with a single course of treatment in patients who achieved therapeutic success.[2] **BLUJEPA was noninferior to NTF in 2 pivotal trials[2]:**

- **EAGLE-2 therapeutic success: BLUJEPA, 50.6% (162/320); NTF, 47.0% (135/287)**
- **EAGLE-3 therapeutic success: BLUJEPA, 58.5% (162/277); NTF, 43.6% (115/264)**

See pages 3-4 for trial design details and page 5 for primary endpoint details.

Additional insights:
Therapeutic response with BLUJEPA was assessed in subgroups of interest, including[2]:

- Age >50 years
- History of recurrent uUTIs
- ESBL+, FQ-R, TMP-SMX-R, or multidrug-resistant *E. coli* isolates

See pages 8-9 for subgroup analysis data.

E. coli=Escherichia coli; ESBL+=extended-spectrum beta-lactamase positive; FQ-R=fluoroquinolone-resistant; NTF=nitrofurantoin; TMP-SMX-R=trimethoprim-sulfamethoxazole-resistant; uUTI=uncomplicated urinary tract infection.

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

QTc Prolongation

- Due to an increase in gepotidacin exposure and the risk of QTc interval prolongation, avoid use of BLUJEPA in patients who have any of the following risk factors:
  - Concomitant use of strong CYP3A4 inhibitors
  - Severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min)
  - Severe hepatic impairment (Child-Pugh Class C)

Acetylcholinesterase Inhibition

- Dysarthria and other adverse reactions potentially attributed to acetylcholinesterase inhibition have been reported with BLUJEPA, a reversible acetylcholinesterase inhibitor. 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 and patients receiving succinylcholine-type or non-depolarizing neuromuscular blocking agents, or systemic anticholinergic medications.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for BLUJEPA.

References: 1. BLUJEPA (gepotidacin) tablets. Prescribing Information. GSK; 2025. **2.** Wagenlehner F, Perry CR, Hooton TM, et al. Oral gepotidacin versus nitrofurantoin in patients with uncomplicated urinary tract infection (EAGLE-2 and EAGLE-3): two randomised, controlled, double-blind, double-dummy, phase 3, non-inferiority trials. *Lancet*. 2024;403(10428):741-755. doi:10.1016/S0140-6736(23)02196-7 **3.** Fromer DL, Luck ME, Cheng WY, et al. Risk factors for empiric treatment failure in US female outpatients with uncomplicated urinary tract infection: an observational study. *J Gen Intern Med*. 2024. doi:10.1007/s11606-024-09029-6 **4.** Patel R, Gupta V, Preib MT, et al. Impact of extended-spectrum β-lactamase-positivity in urine isolates on outcomes in female patients with uncomplicated urinary tract infection. Poster presented at: 33rd European Congress of Clinical Microbiology & Infectious Diseases 2023; April 15-18, 2023; Copenhagen, Denmark. **5.** Wagenlehner F, Perry CR, Hooton TM, et al. Oral gepotidacin versus nitrofurantoin in patients with uncomplicated urinary tract infection (EAGLE-2 and EAGLE-3): two randomised, controlled, double-blind, double-dummy, phase 3, non-inferiority trials. Supplementary appendix. *Lancet*. 2024;403(10428):1-33. doi:10.1016/S0140-6736(23)02196-7 **6.** US Department of Health and Human Services. Food and Drug Administration. *Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment. Guidance for Industry*. Published 2019. Accessed May 27, 2025. https://www.fda.gov/media/129531/download **7.** Data on file, GSK.

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