HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BLUJEPA safely and effectively. See full prescribing information for BLUJEPA.

BLUJEPA (gepotidacin) tablets, for oral use
Initial U.S. Approval: 2025

---------- INDICATIONS AND USAGE----------
BLUJEPA is a triazaacenaphthylene bacterial type II topoisomerase inhibitor 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 the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii* complex, *Staphylococcus saprophyticus,* and *Enterococcus faecalis*. (1.1)

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. (1.2)

----------DOSAGE AND ADMINISTRATION----------
- The recommended dosage of BLUJEPA is 1,500 mg (two 750 mg tablets) taken orally, twice daily (approximately 12 hours apart), for 5 days. (2.1)
- Administer BLUJEPA tablets after a meal to reduce the possibility of gastrointestinal intolerance. (2.1)

---------- DOSAGE FORMS AND STRENGTHS----------
Tablets: 750 mg of gepotidacin. (3)

---------- CONTRAINDICATIONS ----------
A history of severe hypersensitivity to BLUJEPA. (4)

---------- WARNINGS AND PRECAUTIONS----------
- QTc Prolongation: Avoid use of BLUJEPA in patients with a history of QTc prolongation, or with relevant pre-existing cardiac disease, and in patients receiving drugs that prolong the QTc interval. Due to an increase in BLUJEPA exposure, avoid concomitant administration of BLUJEPA with strong CYP3A4 inhibitors and in patients with severe hepatic impairment (Child-Pugh Class C) and in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min). (5.1)
- Acetylcholinesterase inhibition: Dysarthria and other adverse reactions have been reported in patients receiving BLUJEPA. Monitor patients with underlying medical conditions that may be exacerbated by acetylcholinesterase inhibition and patients receiving succinylcholine-type neuromuscular blocking agents, systemic anticholinergic medications, or non-depolarizing neuromuscular blocking agents. (5.2)
- 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. (5.3)
- *Clostridioides difficile* Infection (CDI): CDI has been reported with nearly all systemic antibacterial agents, including BLUJEPA. Evaluate patients who develop diarrhea. (5.4)

---------- 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. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- DRUG INTERACTIONS----------
- CYP3A4 Inhibitors: Avoid coadministration of BLUJEPA with strong CYP3A4 inhibitors. (7.1)
- CYP3A4 Inducers: Avoid coadministration of BLUJEPA with strong CYP3A4 inducers (7.1)
- CYP3A4 Substrates: Avoid coadministration of BLUJEPA with drugs that are extensively metabolized by CYP3A4 and have a narrow therapeutic window. (7.2)
- Digoxin: Due to an increase in digoxin exposures, consider monitoring digoxin serum concentration, as appropriate, with concomitant administration of BLUJEPA. (7.2)

---------- 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. (8.6)
- Hepatic Impairment: Avoid use of BLUJEPA in patients with severe hepatic impairment (Child-Pugh Class C). (8.7)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 3/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Treatment of Uncomplicated Urinary Tract Infections

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 the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii* complex, *Staphylococcus saprophyticus*, and *Enterococcus faecalis*.

1.2 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 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.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage for Female Adult and Pediatric Patients 12 Years of Age and Older Weighing at Least 40 kg

The recommended dosage of BLUJEPA is 1,500 mg (two 750 mg tablets) taken orally, twice daily (approximately 12 hours apart) for 5 days. Administer BLUJEPA tablets after a meal to reduce the possibility of gastrointestinal intolerance *[see Adverse Reactions (6.1), and Clinical Pharmacology (12.3)]*.

2.2 Recommendations Regarding Missed Dose(s)

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.

3 DOSAGE FORMS AND STRENGTHS

Each film coated tablet of BLUJEPA contains 750 mg of gepotidacin. BLUJEPA tablets are yellow, capsule shaped, and debossed with “GS GU3” on one side and plain on the other side.

4 CONTRAINDICATIONS

BLUJEPA is contraindicated in patients with a history of severe hypersensitivity to BLUJEPA *[see Warnings and Precautions (5.3), and Adverse Reactions (6.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 QTc Prolongation

A dose and concentration-dependent prolongation of the QTc interval has been observed with BLUJEPA *[see Clinical Pharmacology (12.2)]*.

Avoid BLUJEPA in patients with a history of QTc interval prolongation or those with relevant pre-existing cardiac disease, patients taking antiarrhythmic agents, or other medications that may potentially prolong the QTc interval *[see Drug Interactions (7.4)]*.

Due to an increase in gepotidacin exposure (C_{max}) and the risk of QTc interval prolongation, avoid concomitant administration of BLUJEPA with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole), in patients with severe hepatic impairment (Child-Pugh Class C), or in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min) *[see Drug Interactions (7.1), and Use in Specific Populations (8.6, 8.7)]*.

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.

5.2 Acetylcholinesterase Inhibition

BLUJEPA is a reversible acetylcholinesterase inhibitor in in vitro laboratory studies. Adverse reactions including dysarthria, presyncope, muscle spasms, diarrhea, nausea, vomiting, abdominal pain, hypersalivation, and hyperhidrosis which are potentially attributed to acetylcholinesterase inhibition, have been observed in clinical trials *[see Adverse Reactions (6.1)]*. Increased cholinergic effects can be associated with severe adverse reactions including atrioventricular block, bradycardia, bronchospasm, seizures/convulsions, and vasovagal syncope. Monitor patients with medical conditions that may be exacerbated by acetylcholinesterase inhibition.

BLUJEPA, as an acetylcholinesterase inhibitor, may exaggerate the neuromuscular effects of succinylcholine-type muscle relaxation during anesthesia. BLUJEPA may exaggerate the effects of other acetylcholinesterase inhibitors. Monitor patients for exaggerated neuromuscular blockade or excessive cholinergic effects.

Because 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 *[see Drug Interactions (7.3)]*.

5.3 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving BLUJEPA *[see Adverse Reactions (6.1)]*. BLUJEPA is contraindicated in patients with a history of severe hypersensitivity to BLUJEPA *[see Contraindications (4)].* Before therapy with BLUJEPA is instituted, carefully inquire about previous hypersensitivity reactions to BLUJEPA. If an allergic reaction to BLUJEPA occurs, discontinue the drug and institute appropriate supportive measures.

5.4 *Clostridioides difficile* Infection

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 *[see Adverse Reactions (6)]*. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDI. Hypertoxin producing isolates of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDI must be considered in all patients who present with diarrhea following

antibacterial drug use. Careful medical history is necessary since 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 instituted as clinically indicated.

5.5 Development of Drug-Resistant Bacteria

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 *[see Indications and Usage (1.2)]*.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- QTc Prolongation *[see Warnings and Precautions (5.1)]*.
- Acetylcholinesterase Inhibition *[see Warnings and Precautions (5.2)]*.
- Hypersensitivity Reactions *[see Warnings and Precautions (5.3)]*.
- *Clostridioides difficile* Infection *[see Warnings and Precautions (5.4)]*.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of BLUJEPA was evaluated in 2 double-blind, active-controlled, randomized trials in female adult and pediatric patients 12 years of age and older with uUTI (Trial 1 and Trial 2). A total of 1,570 patients were treated with BLUJEPA and 1,558 patients were treated with nitrofurantoin (pooled safety populations for BLUJEPA and nitrofurantoin, respectively). Patients received treatment for a median duration of 5 days.

In Trials 1 and 2 (pooled, intent-to-treat [ITT] population), the median age of patients treated with BLUJEPA was 49 (range 13 to 89) years; <1% were <18 years, 77% of patients were 18 to 64 years, 14% were 65 to 74 years, and 8% were ≥75 years. Patients were female (100%) and White (83%), Black or African American (7%), Asian (5%), or American Indian or Alaskan Native (4%); for ethnicity, 33% identified as Hispanic/Latino and 67% as non-Hispanic/Latino. The majority of patients were enrolled from the U.S. (55%).

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation

In the pooled trials (Trials 1 and 2), serious adverse reactions occurred in 1/1,570 (<1%) patient treated with BLUJEPA and 1/1,558 (<1%) patient treated with nitrofurantoin. The serious adverse reaction reported with BLUJEPA was dysarthria. No adverse reaction led to death in either treatment group.

In the pooled trials, adverse reactions leading to discontinuation of treatment occurred in 79/1,570 (5%) of patients treated with BLUJEPA and 30/1,558 (2%) of patients treated with nitrofurantoin. Adverse reactions occurring in >1% of patients leading to treatment discontinuation in patients treated with BLUJEPA included diarrhea (3%) and nausea (1%).

Common Adverse Reactions

Table 1 lists the adverse reactions occurring in ≥1% of patients receiving BLUJEPA in the pooled trials (Trials 1 and 2).

Table 1. Adverse Reactions Occurring in ≥1% of Uncomplicated Urinary Tract Infection Patients Treated with BLUJEPA (Trials 1 and 2 Pooled Data; Safety Population)

Adverse Reaction	BLUJEPA N = 1,570 n (%)	Nitrofurantoin N = 1,558 n (%)
Diarrhea	258 (16)	51 (3)
Nausea	146 (9)	64 (4)
Abdominal pain[a]	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)

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

Diarrhea: In Trial 1 and 2, diarrhea was reported in 258/1,570 (16%) patients receiving BLUJEPA; 11% 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.

Adverse Reactions Occurring in Less than 1% of Patients Receiving BLUJEPA in Trials 1 and 2 (pooled):

Gastrointestinal Disorders: Abdominal distension, dyspepsia (includes epigastric discomfort, eructation)

Nervous System Disorders: Presyncope, dysarthria

Infections and Infestations: Clostridioides difficile infection

Musculoskeletal and Connective Tissue Disorders: Muscle spasms

Vascular Disorders: Hot flush

Cardiac Disorders: Tachycardia

Eye Disorders: Blurred vision

Ear and Labyrinth Disorders: Vertigo

General Disorders and Administration Site Disorders: Fatigue

Investigations: Alanine aminotransferase/aspartate aminotransferase increased

Skin and Subcutaneous Tissue: Rash, hyperhidrosis

Immune System Disorders: Hypersensitivity reactions

Select Adverse Reactions Occurring in Patients Receiving BLUJEPA in Phase 1 and 2 Clinical Studies

Gastrointestinal Disorders: hypersalivation (with oral daily doses ranging from 100 mg to 6,000 mg, which includes not approved doses)

7 DRUG INTERACTIONS

7.1 Effect of Other Drugs on BLUJEPA

CYP3A4 Inhibitors

Due to an increase in gepotidacin exposures, avoid concomitant administration of BLUJEPA with strong inhibitors of CYP3A4 *[see Warnings and Precautions (5.1), and Clinical Pharmacology (12.3)]*.

CYP3A4 Inducers

Due to a decrease in gepotidacin exposures, avoid concomitant administration of BLUJEPA with strong inducers of CYP3A4 *[see Clinical Pharmacology (12.3)]*.

7.2 Effect of BLUJEPA on Other Drugs

CYP3A4 Substrates

Avoid concomitant administration of BLUJEPA with drugs that are extensively metabolized by CYP3A4 and have a narrow therapeutic index (e.g., quinidine, cyclosporine) *[see Clinical Pharmacology (12.3)]*.

Digoxin

Due to an increase in digoxin exposures, consider monitoring digoxin serum concentrations, as appropriate, with concomitant administration of BLUJEPA *[see Clinical Pharmacology (12.3)]*.

7.3 Cholinergic/Anticholinergic Drugs

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. Gepotidacin may augment the effect of other acetylcholinesterase inhibitors (e.g., donepezil). Monitor for exaggerated neuromuscular blockade or excessive cholinergic effects *[see Warnings and Precautions (5.2)]*.

There is potential for an antagonistic effect with systemic anticholinergic medications (e.g., benztropine, oxybutynin) or non-depolarizing neuromuscular blocking agents. Consider the potential for this interaction if BLUJEPA is administered concomitantly with anticholinergic medications *[see Warnings and Precautions (5.2)]*.

7.4 Drugs that Prolong the QTc Interval

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 *[see Warnings and Precautions (5.1)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

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.

Risk Summary

There are no available data on the use of BLUJEPA in pregnant women to evaluate for a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

In embryo-fetal development studies in mice and rats, decreased fetal weights and increased fetal mortality (late resorptions) were observed at exposures about 0.8-to-1-times the maximum recommended human dose (MRHD). In a mouse pre- and postnatal development study, there were no adverse developmental effects at exposures of approximately 3-times the MRHD *(see Data)*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage, in clinically recognized pregnancies, is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data: Gepotidacin did not cause malformations when orally administered in embryo-fetal development studies during organogenesis. Decreased fetal weights were seen in rats dosed orally with 450 mg/kg/day or greater (approximately equal to the MRHD based on AUC extrapolated from nonpregnant rats) and decreased fetal weights and increased late fetal resorptions were seen in mice at oral doses 500 mg/kg/day or greater (approximately 0.8-times the MRHD based on AUC extrapolated from nonpregnant mice).

In a pre- and post-natal development study in mice given oral doses of up to 1,000 mg/kg/day (approximately 3-times the MRHD), there were no gepotidacin effects on parturition, or post-natal growth and development of the offspring.

8.2 Lactation

Risk Summary

There are no data on the presence of gepotidacin in human milk, its effects on the breastfed child, or on milk production. Based on a study in lactating mice, gepotidacin is likely transferred into milk *(see Data).* When a drug is present in animal milk, it is likely that the drug will be present in human milk.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for BLUJEPA and any potential adverse effects on the breastfed child from BLUJEPA or from the underlying maternal condition.

Data

Gepotidacin concentrations in milk have not been measured directly in animals. However, in a pre- and post-natal development study when gepotidacin was orally administered to maternal mice during pregnancy and

lactation, at all tested doses, gepotidacin was detected in the plasma of their nursing offspring (with dosing 200 mg/kg/day or greater, which was expected to result in exposures 0.5-times the MHRD and higher as extrapolated from exposures in nonpregnant mice).

8.4 Pediatric Use

The safety and effectiveness of BLUJEPA for the treatment of uUTI have been established in female pediatric patients 12 years of age and older, weighing at least 40 kg. Use of BLUJEPA in these patients is supported by evidence from adequate and well-controlled studies of BLUJEPA in female adult and pediatric patients 12 years of age and older with uUTI and additional pharmacokinetic data in pediatric patients (12 to <18 years of age) *[see Clinical Pharmacology (12.3), and Clinical Studies (14.1)]*. The safety profile of BLUJEPA in female pediatric patients 12 years of age and older was similar to female adults with uUTI treated with BLUJEPA *[see Adverse Reactions (6.1), and Clinical Studies (14.1)]*.

The safety and effectiveness of BLUJEPA have not been established in pediatric patients less than 12 years of age or weighing less than 40 kg.

8.5 Geriatric Use

Of the total number of patients who received treatment with BLUJEPA in the uUTI studies (Trials 1 and 2), 226 (14%) were 65 to less than 75 years of age and 127 (8%) were 75 years of age and older *[see Clinical Studies (14.1)]*. No overall differences in safety or effectiveness of BLUJEPA were observed between patients 65 years of age and older and younger adult patients, but greater sensitivity of some older individuals cannot be ruled out.

BLUJEPA is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function *[see Warnings and Precautions (5.1), Use in Specific Populations (8.6), and Clinical Pharmacology (12.3)]*.

8.6 Renal Impairment

No dosage adjustment is required in patients with mild renal impairment (eGFR 60 to 89 mL/min) or moderate renal impairment (eGFR 30 to 59 mL/min). 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 *[see Warnings and Precautions (5.1), and Clinical Pharmacology (12.3)]*.

8.7 Hepatic Impairment

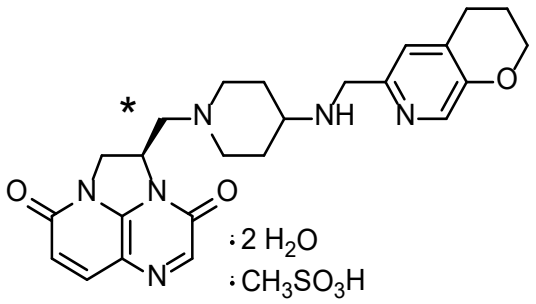
No dosage adjustment is required in patients with mild or moderate hepatic impairment (Child-Pugh Class A/B). Avoid use of BLUJEPA in patients with severe hepatic impairment (Child-Pugh Class C) due to increased exposure to gepotidacin and the risk of QTc prolongation *[see Warnings and Precautions (5.1), and Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

There is a risk of QTc prolongation with overdosage. Intermittent hemodialysis is not likely to substantially remove BLUJEPA from the systemic circulation. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

11 DESCRIPTION

BLUJEPA tablets contain gepotidacin mesylate, a triazaacenaphthylene antibacterial that inhibits bacterial DNA gyrase and topoisomerase IV. The chemical name is (*R*)-2-((4-(((3,4-dihydro-2*H*-pyrano[2,3-*c*]pyridin-6-yl)methyl)amino)piperidin-1-yl)methyl)-1,2-dihydro-3*H*,8*H*-2a,5,8a-triazaacenaphthylene-3,8-dione methanesulfonate dihydrate. The molecular formula is $C_{24}H_{28}N_6O_3 \bullet CH_4O_3S \bullet 2H_2O$ and its molecular mass is 580.66. The structural formula is shown below.



*stereogenic center

Each BLUJEPA oral tablet contains gepotidacin 750 mg (equivalent to 910.7 mg of gepotidacin mesylate [anhydrous]). Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, and yellow iron oxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

BLUJEPA is an antibacterial drug *[see Microbiology (12.4)]*.

12.2 Pharmacodynamics

The 24-hour free-drug AUC to minimum inhibitory concentration (MIC) ratio has been shown in animal infection and in vitro pharmacokinetic -pharmacodynamic (PK-PD) models to be the PK-PD index predictive of gepotidacin antibacterial efficacy.

Cardiac Electrophysiology

The effect of gepotidacin on the QTc interval was evaluated in a randomized, active (moxifloxacin 400 mg) and placebo-controlled, double-blind cross-over trial in healthy subjects who received single intravenous (IV) infusions of gepotidacin over 2 hours. A dose- and concentration-dependent QTc prolongation effect of gepotidacin was observed. The mean placebo-corrected change from baseline heart rate values around T_{max} were approximately 6 bpm at 1,000 mg IV (not an approved dosing regimen and route of administration) and approximately 10 bpm at 1,800 mg IV (not an approved dosing regimen and route of administration). The mean placebo-corrected change from baseline QTcF values around T_{max} were 12 msec at 1,000 mg IV and 22 msec at 1,800 mg IV *[see Warnings and Precautions (5.1)]*. The C_{max} of gepotidacin following a single 1,000 mg IV dose (not an approved dosing regimen and route of administration) is approximately 1.7 times that of the C_{max} at steady state for the 1,500 mg oral dose twice daily.

12.3 Pharmacokinetics

Pharmacokinetic Parameters

The pharmacokinetic properties of gepotidacin are summarized in Table 2 as mean (standard deviation [SD]) unless otherwise specified.

Table 2. Pharmacokinetic Parameters of Gepotidacin

General Information	
Exposure	
Cmax (mcg/mL)[a]	4.2 (1.0)
AUC_{0-12} (mcg*hour/mL)[a]	22.8 (4.8)
Dose Proportionality	Approximately dose proportional from 1,500 to 3,000 mg
Accumulation	40% and steady state was achieved by Day 3
Absorption	
Absolute Bioavailability	~45%
Tmax, (hours)	~2.0
Effect of food (moderate fat meal)[b]	No clinically significant effect on PK
Distribution	
Vss (L)[a]	172.9 (42.5)
Plasma Protein Binding	~25 to ~41%
Elimination	
Terminal Half-life (hours)[a]	9.3 (1.3)
Total Clearance (L/hour)[a]	33.4 (6.7)
Metabolism	
Primary Pathway	Oxidative metabolism mediated by CYP3A4, producing several circulating metabolites
Major Metabolite (%)	M4 which is ~11% of circulating drug-related materials
Excretion	
Feces	~52% (30% unchanged drug)
Urine	~31% (20% unchanged drug; major route of elimination for absorbed gepotidacin)

[a] Pharmacokinetic parameters are presented at steady state in patients with uUTI and eGFR greater than or equal to 90 mL/min after oral administration of BLUJEPA 1500 mg every 12 hours over 5 days.

[b] Studies evaluating the effect on food were performed with standard and moderate fat meal. Clinical studies were not performed with a high fat meal (1000 calories, 50% fat).

Specific Populations

Modelling and simulation analyses of gepotidacin showed no clinically relevant effect of age (12 to <18 years of age or 65 to 89 years of age), sex, race, or body weight (range: 40 kg to 140 kg) on gepotidacin exposure *[see Use in Specific Populations (8.4), (8.5)]*.

Patients with Renal Impairment: The pharmacokinetics of gepotidacin were evaluated in subjects with moderate renal impairment (eGFR 30 to 59 mL/min) and in subjects with severe renal impairment/end stage renal disease

(ESRD) on intermittent hemodialysis and not on intermittent hemodialysis (eGFR <30 mL/min). Gepotidacin plasma C_{max} and AUC in subjects with moderate renal impairment were 1.2-fold and 1.5-fold higher than matched healthy controls, respectively. Gepotidacin plasma C_{max} and AUC in severe renal impairment/ESRD not on intermittent hemodialysis were 1.7-fold and 2.1-fold higher than matched healthy controls, respectively. Gepotidacin plasma C_{max} and AUC in ESRD subjects requiring intermittent hemodialysis were 2.3-fold and 2.5-fold higher before intermittent hemodialysis than healthy matching subjects, respectively, and were 6.2-fold and 4.2-fold higher after intermittent hemodialysis than matched healthy controls, respectively *[see Use in Specific Populations (8.6)]*.

Patients with Hepatic Impairment: Moderate hepatic impairment did not have a clinically relevant effect on gepotidacin pharmacokinetics. In subjects with severe hepatic impairment compared with subjects with normal hepatic function, gepotidacin plasma exposure parameters (C_{max} and AUC) were increased by approximately 1.9-fold and 1.7-fold, respectively *[see Use in Specific Populations (8.7)]*.

Drug Interaction Studies

Clinical Drug Interaction Studies

Effect of CYP3A4 Inhibitors on the Pharmacokinetics of Gepotidacin: Concomitant administration of a strong inhibitor of CYP3A4 (itraconazole; 200 mg per day for 3 days), and a single 1,500 mg dose of BLUJEPA resulted in an increase in the maximum concentration (C_{max}) of gepotidacin of approximately 1.4-fold and area under the curve (AUC) of approximately 1.5-fold *[see Drug Interactions (7.1)]*.

Effect of CYP3A4 Inducers on the Pharmacokinetics of Gepotidacin: Concomitant administration of BLUJEPA (single 1,500 mg dose) with a strong CYP3A4 inducer (rifampin; 600 mg once daily for 7 days) resulted in a decrease of 52% in gepotidacin plasma AUC(0-∞) *[see Drug Interactions (7.2)]*.

Effect of BLUJEPA on Pharmacokinetics of Other Drugs: Concomitant administration of a single 0.5 mg dose of digoxin with two 3,000 mg doses of BLUJEPA (an in vitro P-glycoprotein inhibitor), given 12 hours apart (not an approved dosage of BLUJEPA), resulted in a 1.5-fold increase in the digoxin C_{max} (at 3 hours post dose), a 1.1-fold increase in the digoxin AUC(0-∞), and a delayed digoxin T_{max} *[see Drug Interactions (7.2)]*.

Concomitant administration of midazolam (2 mg single dose) with BLUJEPA (2 doses of 3,000 mg, given 12 hours apart; not an approved dosage of BLUJEPA) resulted in a 1.9-fold increase in midazolam AUC(0-∞) *[see Drug Interactions (7.2)]*.

In-Vitro Drug Interaction Studies

In vitro, gepotidacin was not an inducer of CYP1A2, 2B6 or 3A4. In vitro, gepotidacin is not a substrate of any of the hepatic organic anion transporting polypeptides (OATPs) 1B1, 1B3, and 2B1, organic anion transporters (OATs) OAT1, OAT2 and OAT3, organic cation transporters (OCTs) OCT2 and OCT3.

In Vitro Studies Where Drug Interaction Potential Was Not Further Evaluated Clinically

In vitro, gepotidacin inhibited multidrug and toxin extrusion (MATEs) MATE1 (IC_{50}=16.6 μM), and MATE2-K (IC_{50}=6.9 μM). In vitro, gepotidacin is a substrate of breast cancer resistance protein (max flux rate ratio of 11.0).

12.4 Microbiology

Mechanism of Action

BLUJEPA is a triazaacenaphthylene antibacterial that inhibits Type II topoisomerases including bacterial topoisomerase II (DNA gyrase) and topoisomerase IV, thereby inhibiting DNA replication.

Gepotidacin has bactericidal activity against pathogens as determined by time-kill studies. In vitro studies demonstrated a gepotidacin post-antibiotic effect ranging from 1.8 to 2.2 hours for *E. coli*, 1 to >6.6 hours for *K. pneumoniae*, 1.4 to 3 hours for *P. mirabilis*, 1 to 2.6 hours for *C. freundii*, 2.7 to 4.3 hours for *S. saprophyticus,* and 1.2 to 2.7 hours for *E. faecalis* at 5 times the MIC.

Resistance

Although no clear mechanisms of resistance have been identified for gepotidacin, potential mechanisms that may impact gepotidacin activity are gepotidacin-specific alterations of DNA gyrase (*gyrA*, *gyrB*) and/or topoisomerase IV (*parC*, *parE*) gene targets, plasmid-mediated quinolone resistance genes (especially *qnr*), and efflux. The following amino acids may be important for gepotidacin activity GyrA P35, V44, D82, A175, GyrB D426, P445 and ParC D79 as shown through studies with isogenic mutants in *E. coli* and *K. pneumoniae*. A single target-specific mutation may not significantly impact gepotidacin activity. The relationship between gepotidacin and fluoroquinolone susceptibility does not appear to include amino acid substitutions in GyrA and ParC that are known to reduce fluoroquinolone susceptibility in *E. coli*. Gepotidacin activity against *E. coli* and *K. pneumoniae* is unrelated to beta-lactam resistance mechanisms.

The frequency of resistance development to gepotidacin due to spontaneous mutations in the gram-negative and gram-positive uropathogens tested in vitro at 10 times MIC ranged from 10^{-9} to 10^{-10}.

Target-specific cross-resistance with other classes of antibacterial drugs has not been identified; therefore, isolates resistant to other drugs may be susceptible to gepotidacin. However, isolates of Enterobacterales with ≥4-fold increases in gepotidacin MIC have been identified in vitro and in clinical studies.

During clinical studies, gepotidacin demonstrated activity against some isolates of the following multilocus sequence typing (MLST) for *E. coli*: ST10, ST131, ST1193, ST69, ST95 and ST73.

Interaction with Other Antimicrobials

In in vitro studies, no antagonism against Enterobacterales or gram-positive isolates was observed for gepotidacin in combination with multiple antibacterial drugs, including fluoroquinolones, sulfonamides, cephalosporins, macrolides, tetracyclines, aminoglycosides, glycopeptides, carbapenems, nitrofurans, monobactams, and oxazolidinones.

Antimicrobial Activity

Gepotidacin has been shown to be active against most isolates of the following microorganisms, both in vitro and in clinical infections *[see Indications and Usage (1)]*:

Aerobic bacteria

Gram-positive bacteria

Enterococcus faecalis

Staphylococcus saprophyticus

Gram-negative bacteria

Citrobacter freundii complex

Escherichia coli

Klebsiella pneumoniae

The following in vitro data are available, but their clinical significance is unknown. At least 90 percent of the following bacteria exhibit an in vitro minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for gepotidacin against isolates of similar genus or organism group. However, the efficacy of gepotidacin in treating clinical infections caused by these bacteria has not been established in adequate and well-controlled clinical trials.

Aerobic bacteria

Gram-negative bacteria

Citrobacter koseri

Klebsiella aerogenes

Klebsiella oxytoca/ Raoltella ornithinolytica

Morganella morganii

Proteus mirabilis

Providencia rettgeri

Susceptibility Test Methods

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: https://www.fda.gov/STIC.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long term carcinogenicity studies have not been conducted with gepotidacin.

Mutagenesis

Gepotidacin was positive in an in vitro micronucleus test in human peripheral blood lymphocytes and in an L5178Y mouse lymphoma assay, consistent with the known in vitro clastogenic effects of topoisomerase inhibitors in in vitro mammalian cell assays. Gepotidacin was negative in an in vivo micronucleus test or Comet assay in rat. Based on an overall weight of evidence, gepotidacin is unlikely to be genotoxic.

Impairment of Fertility

In animal studies with gepotidacin, there were no adverse effects on fertility in male and female rats treated for approximately 3 weeks at 4-times the exposure at the MRHD (AUC extrapolated from rats orally administered the same dose for up to 4 weeks). There were no effects on spermatogenesis in rats and dogs at 4 and 5 times the exposure at MRHD, respectively, when treated for up to 13 weeks.

14 CLINICAL STUDIES

14.1 Uncomplicated Urinary Tract Infections

A total of 3,136 female patients with uUTI were randomized in 2 multicenter, parallel-group, double-blind, double-dummy, non-inferiority (NI) trials (Trial 1 [NCT04020341] and Trial 2 [NCT04187144]). Both trials compared BLUJEPA 1,500 mg (administered orally twice daily with food for 5 days) to nitrofurantoin 100 mg (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 (e.g., pyelonephritis, urosepsis) were excluded.

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 microbiological ITT nitrofurantoin-susceptible (micro-ITTS) population, which included all patients who received at least 1 dose of study medication, had at least 1 baseline qualifying uropathogen ($\geq 10^5$ colony-forming units [CFU]/mL), 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 $\geq 10^5$ CFU/mL reduced to $<10^3$ CFU/mL without the patient receiving other systemic antimicrobials.

Both trials demonstrated non-inferiority of BLUJEPA to nitrofurantoin for composite response (Table 3).

In Trial 1, the micro-ITTS population consisted of 634 female patients with uUTI (n = 336 BLUJEPA; n = 298 nitrofurantoin). The median age of patients was 54 years, 57% were >50 years of age, 84% were White, 40% had a history of recurrent infection. The U.S. enrolled the greatest percentage of patients (39%). Patient demographic and baseline characteristics were generally balanced between treatment groups *[see Adverse Reactions (6.1)]*.

In Trial 2, the micro-ITTS population consisted of 567 female patients with uUTI (n = 292 BLUJEPA; n = 275 nitrofurantoin). The median age of patients was 51 years, 52% were >50 years of age, 85% were White, 41% had history of recurrent infection. The majority of patients (67%) were enrolled from the U.S. Patient demographic and baseline characteristics were generally balanced between treatment groups *[see Adverse Reactions (6.1)]*.

Table 3 summarizes the composite response, clinical cure, and microbiological response rates at the TOC visit for Trials 1 and 2 in the micro-ITTS population.

Table 3. Composite Response, Clinical Cure, and Microbiological Response Rates at the Test-of-Cure Visit (Micro-ITTS Population)

Study Endpoint	BLUJEPA n/N (%)	Nitrofurantoin n/N (%)	Treatment Difference (95% CI)[b]
Trial 1			
Composite response[a]	174/336 (51.8)	140/298 (47.0)	5.3 (-2.4, 13.0)
Clinical cure	224/336 (66.7)	196/298 (65.8)	1.5 (-5.8, 8.8)
Microbiological response	244/336 (72.6)	199/298 (66.8)	6.0 (-1.2, 13.1)
Trial 2			
Composite response[a]	172/292 (58.9)	121/275 (44.0)	14.4 (6.4, 22.4)
Clinical cure	199/292 (68.2)	175/275 (63.6)	4.3 (-3.4, 12.0)
Microbiological response	213/292 (72.9)	158/275 (57.5)	15.5 (7.9, 23.1)

Micro-ITTS = Microbiological Intent to Treat nitrofurantoin-susceptible; CI = confidence interval.

[a] BLUJEPA was non-inferior to nitrofurantoin in both studies. The determination of Trial 1 non-inferiority was based on a planned interim analysis of 607 subjects in Micro-ITTS population. The determination of Trial 2 non-inferiority was based on a planned interim analysis of 541 subjects in Micro-ITTS population.

[b] Treatment difference (BLUJEPA – nitrofurantoin) calculated using Miettinen and Nurminen Summary Score method adjusting for age group and recurrent/non-recurrent infection status combinations.

Table 4 summarizes the composite response rates at the TOC Visit for the most common baseline uropathogens across both trials in the micro-ITTS population.

Table 4. Composite Response Rates at the Test-of-Cure Visit by Baseline Uropathogen (Trial 1 and Trial 2 Pooled; Micro-ITTS Population)[a]

Pathogen[b]	BLUJEPA[a] n/N (%)	Nitrofurantoin[a] n/N (%)
Escherichia coli	312/566 (55.1)	234/520 (45.0)
Klebsiella pneumoniae	6/14 (42.9)	6/16 (37.5)
Citrobacter freundii complex	8/12 (66.7)	2/5 (40.0)
Staphylococcus saprophyticus	9/15 (60.0)	11/14 (78.6)
Enterococcus faecalis	8/14 (57.1)	2/7 (28.6)

Micro-ITTS = Microbiological Intent to Treat nitrofurantoin-susceptible;

[a] A patient is counted once under a uropathogen category if multiple qualifying uropathogens within that category are isolated at baseline for the patient.

[b] Patients may have been infected with 1 to 2 uropathogens at baseline.

16 HOW SUPPLIED/STORAGE AND HANDLING

BLUJEPA tablets are supplied as yellow, film-coated, capsule-shaped tablets debossed with “GS GU3” on one side and plain on the other side, containing 750 mg of gepotidacin.

Bottle of 20 tablets (NDC 0173-0922-45).

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Important Administration Instructions

Counsel patients to take BLUJEPA after a meal to reduce the possibility of gastrointestinal intolerance *[see Dosage and Administration (2.1)]*.

Prolongation of the QTc Interval

Counsel patients to inform their healthcare provider of any personal or family history of QTc prolongation or proarrhythmic conditions such as hypokalemia, bradycardia, or recent myocardial ischemia, or if they are taking any antiarrhythmic agents. Advise patients to notify their healthcare providers if they have any symptoms of prolongation of the QTc interval, including prolonged heart palpitations or a loss of consciousness *[see Warnings and Precautions (5.1)]*.

Acetylcholinesterase Inhibition

Counsel patients that BLUJEPA can cause dysarthria and other symptoms such as presyncope, muscle spasms, diarrhea, nausea, vomiting, abdominal pain, hypersalivation, and hyperhidrosis. Advise patients to inform their healthcare provider if they experience these symptoms or if they have an underlying medical condition that may be exacerbated by acetylcholinesterase inhibition or are planning to receive anesthesia where they may receive neuromuscular blocking agents, or if they are receiving other acetylcholinesterase inhibitors, or systemic anticholinergic medications *[see Warnings and Precautions (5.2), and Drug Interactions (7.3)]*.

Hypersensitivity Reactions

Advise patients that hypersensitivity reactions, including anaphylaxis, could occur and require immediate treatment. Advise patients to inform their healthcare provider about any previous hypersensitivity reactions to BLUJEPA *[see Warnings and Precautions (5.3)]*.

Potentially Serious Diarrhea

Counsel patients that diarrhea is a common problem caused by antibacterials, including BLUJEPA, and it usually ends when the antibacterial is discontinued. Sometimes, frequent watery or bloody diarrhea may occur and may be a sign of a more serious intestinal infection. If severe watery or bloody diarrhea develops, patients should contact their healthcare provider *[see Warnings and Precautions (5.4)]*.

Antibacterial Resistance

Patients should be counseled that antibacterial drugs, including BLUJEPA, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When BLUJEPA is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may: (1) decrease the effectiveness of the immediate treatment, and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by BLUJEPA or other antibacterial drugs in the future *[see Warnings and Precautions (5.5)]*.

Drug Interactions

Advise patients of the potential interactions other medications may have with BLUJEPA or the effect BLUJEPA may have on other medications, as these may result in decreased effectiveness or increased toxicities of either BLUJEPA or the other medications. Patients should alert their healthcare provider if they are currently taking any medications, including herbal nutritional supplements, or are prescribed new medications during treatment with BLUJEPA *[see Warnings and Precautions (5.1), Drug Interactions (7), and Clinical Pharmacology (12.3)]*.

Pregnancy

Advise patients who are exposed to BLUJEPA during pregnancy to contact GlaxoSmithKline at 1-888-825-5249 *[see Use in Specific Populations (8.1)]*.

Manufactured for

GlaxoSmithKline
Durham, NC 27701

BLJ:1PI

MEDICATION GUIDE

BLUJEPA (blu – JEP – ah)

(gepotidacin)

tablets, for oral use

What is the most important information I should know about BLUJEPA?

BLUJEPA, an antibiotic, can cause serious side effects, including:

- **QTc prolongation.** BLUJEPA can cause QTc prolongation (also called prolonged QTc interval) that can lead to serious heart rhythm problems, including Torsade de Pointes. There may be changes in your heartbeat (a fast or irregular heartbeat).

  Before starting BLUJEPA, tell your healthcare provider if you:

  - or anyone in your family has ever had a heart rhythm problem (problem with heart rate or heartbeat) or QTc prolongation.
  - are taking any medicines to treat heart rhythm problems. Using these medicines with BLUJEPA may cause serious side effects. If you are not sure, ask your healthcare provider.

Tell your healthcare provider right away if you have any of the following symptoms:

- fast, pounding, or uneven heartbeat
- feeling dizzy
- you lose consciousness (pass out)
- feeling lightheaded
- feeling faint

- **cholinergic effects.** BLUJEPA can cause an increase of a certain chemical in your nervous system, called acetylcholine. When acetylcholine is increased in your nervous system it may cause symptoms (cholinergic effects).

The following symptoms may be caused by an increase in acetylcholine:

- diarrhea
- vomiting
- feeling faint
- trouble saying words clearly
- muscle spasms
- nausea
- more saliva in the mouth
- more sweating
- stomach pain

Call your healthcare provider right away if you have trouble saying words clearly, have shortness of breath, or if you faint. These symptoms may be cholinergic effects of BLUJEPA.

Increased acetylcholine can also be connected to other symptoms. Call your healthcare provider right away if you have any of these additional symptoms.

- irregular heartbeat (heart block)
- slow heartbeat (bradycardia)
- seizures
- fainting
- chest tightness causing difficulty breathing

- **allergic reactions.** Allergic reactions can happen in people who take BLUJEPA including a severe allergic reaction called anaphylaxis. Stop taking BLUJEPA and get medical help right away if you have any symptoms of a severe allergic reaction, including:
  - hives
  - feeling faint or dizzy
  - rash
  - swelling of your lips, tongue, or throat
- **diarrhea.** Diarrhea is a common side effect caused by antibiotics including BLUJEPA. The diarrhea usually stops after the antibiotic is stopped. In some cases, diarrhea may be caused by *Clostridioides difficile infection* (CDI). CDI is a severe infection of the intestines (bowels) that can happen up to 2 months after finishing treatment with antibiotic medicines, including BLUJEPA. CDI can be life-threatening and can lead to death. Do not take medicines to treat

diarrhea without checking first with your healthcare provider. Call your healthcare provider right away if you have the following symptoms:

- stomach cramps
- fever
- watery diarrhea
- diarrhea that does not go away
- bloody stools

What is BLUJEPA?

BLUJEPA is an antibiotic used to treat women and girls 12 years of age and older weighing at least 88 pounds who have an infection of the bladder (known as an uncomplicated urinary tract infection [uUTI]) caused by certain types of bacteria. It is not known if BLUJEPA is safe and effective in children under 12 years of age or weighing less than 88 pounds.

Do not take BLUJEPA if:

you have had a severe allergic reaction to BLUJEPA. See the end of this Medication Guide for a complete list of ingredients in BLUJEPA.

Before taking BLUJEPA, tell your healthcare provider about all of your medical conditions, including if you:

- have heart rhythm problems. **See "What is the most important information I should know about BLUJEPA?"**
- have a slow heartbeat (bradycardia).
- have recently had a heart attack.
- have low potassium in your blood (hypokalemia).
- are planning to have a medical or surgical procedure that puts you to sleep (general anesthesia) that will use a type of medicine given through your veins (I.V.) that relaxes your muscles.
- have liver problems.
- have kidney problems, kidney failure, or are on dialysis.
- are pregnant or plan to become pregnant. It is not known if BLUJEPA will harm your unborn baby.

Tell your healthcare provider if you become pregnant or think you are pregnant during your treatment with BLUJEPA.

- **Pregnancy Exposure Registry:** There is a pregnancy exposure registry for women who are exposed to BLUJEPA during pregnancy. The purpose of this registry is to check the health of you and your baby. If you are pregnant or become pregnant during your treatment with BLUJEPA, talk to your healthcare provider about registering with GlaxoSmithKline. You can register by calling GlaxoSmithKline at 1-888-825-5249.
- are breastfeeding or plan to breastfeed. It is not known if BLUJEPA passes into breast milk. Talk to your healthcare provider about the best way to feed your baby during your treatment with BLUJEPA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BLUJEPA and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take medicines to treat heart rhythm problems.

Ask your healthcare provider or pharmacist, if you are not sure if you are taking any of these medicines. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take BLUJEPA?

- Take BLUJEPA exactly as your healthcare provider tells you to take it. Check with your healthcare provider if you are not sure.
- Take two tablets of BLUJEPA by mouth, 2 times each day (about 12 hours apart), for 5 days.
- Take BLUJEPA after a meal to decrease the chance of stomach upset.
- If you miss a dose, take it as soon as possible, then continue your treatment as before. Do not take 2 doses to make up for a missed dose.

- If you take too much BLUJEPA, call the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.
- Take the full course of treatment with BLUJEPA. Do not stop taking BLUJEPA during your treatment unless your healthcare provider tells you to, even if you are feeling better. If you do not complete your full course of treatment, the infection may come back.

What are the possible side effects of BLUJEPA?

BLUJEPA can cause serious side effects including:

- **See the "What is the most important information I should know about BLUJEPA?"**

The most common side effects of BLUJEPA include:

- diarrhea
- nausea
- stomach pain
- gas
- headache
- soft stools
- dizziness
- vomiting
- yeast infections

These are not all the possible side effects of BLUJEPA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BLUJEPA?

- Store BLUJEPA tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep BLUJEPA and all medicines out of the reach of children.

General information about the safe and effective use of BLUJEPA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BLUJEPA for a condition for which it was not prescribed. Do not give BLUJEPA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about BLUJEPA that is written for health professionals.

What are the ingredients in BLUJEPA?

Active ingredient: gepotidacin mesylate

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide and yellow iron oxide.

Manufactured for:

GSK

GlaxoSmithKline, Durham, NC 27701

BLJ:1MG

For more information, call 1-888-825-5249 or go to www.gsk.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: March 2025