

BLUJEP- gepotidacin tablet, film coated

GlaxoSmithKline LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BLUJEP- safely and effectively. See full prescribing information for BLUJEP-.

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

RECENT MAJOR CHANGES

Indications and Usage (1.2)	12/2025
Dosage and Administration (2.2)	12/2025
Warnings and Precautions (5.1)	12/2025

INDICATIONS AND USAGE

BLUJEP- is a triazaacenaphthylene bacterial type II topoisomerase inhibitor indicated for the treatment of the following infections caused by susceptible microorganisms:

- Uncomplicated urinary tract infections (uUTI) in female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg). (1.1)
- Uncomplicated urogenital gonorrhea in adult and pediatric patients 12 years of age and older weighing at least 45 kilograms who have limited or no alternative treatment options. Approval of this indication is based on limited clinical safety data for this indication. (1.2, 6.1)

Usage to Reduce Development of Drug-Resistant Bacteria

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BLUJEP- and other antibacterial drugs, BLUJEP- should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. (1.3)

DOSAGE AND ADMINISTRATION

- uUTI: The recommended dosage of BLUJEP- is 1,500 mg (two 750 mg tablets) taken orally, twice daily (approximately 12 hours apart), for 5 days. (2.1)
- Uncomplicated Urogenital Gonorrhea: The recommended dosage of BLUJEP- is 3,000 mg (four 750 mg tablets) taken orally, followed by a second dose of 3,000 mg (four 750 mg tablets) approximately 12 hours later. (2.2)
- Administer BLUJEP- tablets after a meal to reduce the possibility of gastrointestinal intolerance. (2.3)

DOSAGE FORMS AND STRENGTHS

Tablets: 750 mg of gepotidacin. (3)

CONTRAINDICATIONS

A history of severe hypersensitivity to BLUJEP-. (4)

WARNINGS AND PRECAUTIONS

- QTc Prolongation:
- Avoid use of BLUJEP- in patients with a history of QTc prolongation, or with relevant pre-existing cardiac disease, or in patients receiving drugs that prolong the QTc interval. (5.1)
- Due to an increase in gepotidacin exposure and the risk of QTc interval prolongation, avoid use of BLUJEP- in patients who have any of the following risk factors: (5.1, 7.1, 8.6, 8.7)
- Concomitant use of strong CYP3A4 inhibitors
- Severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min)
- Severe hepatic impairment (Child-Pugh Class C)
- Additionally, avoid BLUJEP- in uncomplicated urogenital gonorrhea patients, who have any of the following risk factors for increased gepotidacin exposure: (5.1, 7.1, 8.6, 8.7)
- Concomitant use of moderate CYP3A4 inhibitors
- Two or more of the following risk factors: Body weight between 45 kilograms and 60 kilograms, Moderate renal impairment (eGFR 30 to 59 mL/min), Moderate hepatic impairment (Child-Pugh Class B)

- Acetylcholinesterase Inhibition: Dysarthria and other adverse reactions have been reported in patients receiving BLUJEP A. 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 BLUJEP A. If an allergic reaction to BLUJEP A 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 BLUJEP A. Evaluate patients who develop diarrhea. (5.4)

ADVERSE REACTIONS

- uUTI: The most common adverse reactions occurring in $\geq 1\%$ of patients are diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candidiasis. (6.1)
- Uncomplicated Urogenital Gonorrhea: The most common adverse reactions occurring in $\geq 2\%$ of patients are diarrhea, nausea, abdominal pain, vomiting, flatulence, dizziness, soft feces, headache, fatigue, and hyperhidrosis. (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: Increase gepotidacin exposure. (7.1)
- Strong CYP3A4 inhibitors: Avoid concomitant use of BLUJEP A with strong CYP3A4 inhibitors. (5.1, 7.1)
- Moderate CYP3A4 inhibitors: Avoid concomitant use of BLUJEP A with moderate CYP3A4 inhibitors in patients with uncomplicated urogenital gonorrhea. (5.1, 7.1)
- CYP3A4 Inducers: Decrease gepotidacin exposure. (7.1)
- For uUTI: Avoid concomitant use of BLUJEP A with strong CYP3A4 inducers. (7.1)
- For uncomplicated urogenital gonorrhea: Avoid concomitant use of BLUJEP A with strong and moderate CYP3A4 inducers. (7.1)
- CYP3A4 Substrates: Avoid concomitant use of BLUJEP A with drugs that are extensively metabolized by CYP3A4 where minimal concentration changes may lead to serious adverse reactions. (7.2)
- Digoxin: Due to an increase in digoxin exposures, consider monitoring digoxin serum concentration, as appropriate, with concomitant administration of BLUJEP A. (7.2)

USE IN SPECIFIC POPULATIONS

- Renal Impairment: Avoid use of BLUJEP A in patients with severe renal impairment with eGFR < 30 mL/min, including those receiving dialysis. (8.6)
- Hepatic Impairment: Avoid use of BLUJEP A in patients with severe hepatic impairment (Child-Pugh Class C). (8.7)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 2/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Treatment of Uncomplicated Urinary Tract Infections

BLUJEP A is indicated in female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) 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*.

1.2 Treatment of Uncomplicated Urogenital Gonorrhea

BLUJEP A is indicated in adult and pediatric patients 12 years of age and older weighing at least 45 kilograms (kg) 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 BLUJEP A [see *Adverse Reactions* (6.1)].

1.3 Usage to Reduce Development of Drug-Resistant Bacteria

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BLUJEP A and other antibacterial drugs, BLUJEP A 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 for Uncomplicated UTI

The recommended dosage of BLUJEP A is 1,500 mg (two 750 mg tablets) taken orally, twice daily (approximately 12 hours apart) for 5 days in female adult and pediatric patients 12 years of age and older with uncomplicated uUTI [see *Dosage and Administration* (2.3)].

2.2 Recommended Dosage for Adult and Pediatric Patients 12 Years of Age and Older Weighing at Least 45 kg for Uncomplicated Urogenital Gonorrhea

The recommended dose of BLUJEP A is 3,000 mg (four 750 mg tablets) taken orally, followed by a second dose of 3,000 mg (four 750 mg tablets) approximately 12 hours later in adult and pediatric patients 12 years of age and older weighing at least 45 kg with uncomplicated urogenital gonorrhea [see *Dosage and Administration* (2.3)].

Do not increase the dose, extend the duration of treatment, or reduce the interval between doses due to the risk of QTc interval prolongation [see *Warnings and Precautions* (5.1)].

2.3 Important Administration Instructions

Administer BLUJEP A tablets after a meal to reduce the possibility of gastrointestinal intolerance [see *Adverse Reactions* (6.1), *Clinical Pharmacology* (12.3)].

2.4 Recommendations Regarding Missed Dose(s)

If a dose is missed, instruct patients to take the missed dose as soon as possible. For uUTI, do **not** double the dose to make up for a missed dose.

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

BLUJEP A is contraindicated in patients with a history of severe hypersensitivity to BLUJEP A [see *Warnings and Precautions (5.3), 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 BLUJEP A [see *Clinical Pharmacology (12.2)*].

Avoid BLUJEP A 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 BLUJEP A in patients who have any of the following risk factors [see *Drug Interactions (7.1), Use in Specific Populations (8.6, 8.7)*]:

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

Additionally, avoid BLUJEP A in uncomplicated urogenital gonorrhea patients who also have any of the following risk factors for increased gepotidacin exposure [see *Drug Interactions (7.1), Use in Specific Populations (8.6, 8.7)*]:

- Concomitant use of moderate CYP3A4 inhibitors
- Two or more of the following risk factors:
 - Body weight between 45 kg and 60 kg
 - Moderate renal impairment (eGFR 30 to 59 mL/min)
 - Moderate hepatic impairment (Child-Pugh Class B)

If administration of BLUJEP A 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, 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 [see *Adverse Reactions (6.1)*]. 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, 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 (1.3)*].

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.

Clinical Trial Experience in Patients with Uncomplicated UTI

The safety of BLUJEP A 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 BLUJEP A and 1,558 patients were treated with nitrofurantoin (pooled safety populations for BLUJEP A 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 BLUJEP A 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%) uUTI patients treated with BLUJEP A and 1/1,558 (<1%) uUTI patients treated with nitrofurantoin. The serious adverse reaction reported with BLUJEP A 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%) uUTI patients treated with BLUJEP A and 30/1,558 (2%) uUTI patients treated with nitrofurantoin. Adverse reactions occurring in >1% of patients leading to treatment discontinuation in patients treated with BLUJEP A included diarrhea (3%) and nausea (1%).

Common Adverse Reactions: Table 1 lists the adverse reactions occurring in ≥1% of uUTI patients receiving BLUJEP A in the pooled trials (Trials 1 and 2).

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

	BLUJEP A N = 1,570	Nitrofurantoin N = 1,558
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Adverse Reaction	n (%)	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 Trials 1 and 2, diarrhea was reported in 258/1,570 (16%) uUTI 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 uUTI 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 uUTI 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)

Clinical Trial Experience in Patients with Uncomplicated Urogenital Gonorrhoea

The safety of BLUJEPa was evaluated in a randomized, active-controlled trial (Trial 3) comparing BLUJEPa to ceftriaxone and azithromycin in adult and pediatric patients 12 years of age and older with uncomplicated urogenital gonorrhoea. A total of 309 patients received at least one dose of BLUJEPa (safety population).

In Trial 3 (ITT population), the median age of patients randomized to receive BLUJEP A was 33 (range 16 to 64) years; >99% of patients were 18 to 65 years (no patients were >65 years). Overall, patients randomized to receive BLUJEP A treatment were predominately male (89%) and White (74%).

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation: No serious adverse reactions occurred in uncomplicated urogenital gonorrhoea patients treated with BLUJEP A in Trial 3. Adverse reactions leading to discontinuation of treatment occurred in 3/309 (<1%) of uncomplicated urogenital gonorrhoea patients treated with BLUJEP A.

Common Adverse Reactions: Table 2 lists the adverse reactions occurring in $\geq 2\%$ of uncomplicated urogenital gonorrhoea patients receiving BLUJEP A in Trial 3.

Table 2. Adverse Reactions Occurring in $\geq 2\%$ of Uncomplicated Urogenital Gonorrhoea Patients Treated with BLUJEP A (Trial 3; Safety Population)

Adverse Reaction	BLUJEP A N = 309 n (%)	Ceftriaxone and Azithromycin N = 313 n (%)
Diarrhea	151 (49)	30 (10)
Nausea	73 (24)	9 (3)
Abdominal pain ^a	25 (8)	6 (2)
Vomiting	20 (6)	2 (<1)
Flatulence	20 (6)	1 (<1)
Dizziness	16 (5)	2 (<1)
Soft feces	16 (5)	1 (<1)
Headache	10 (3)	8 (3)
Fatigue ^b	10 (3)	0
Hyperhidrosis	7 (2)	0

^a Abdominal pain includes abdominal pain, abdominal pain upper, and abdominal discomfort.

^b Fatigue includes fatigue and lethargy.

Diarrhea: In Trial 3, diarrhea was reported in 151/309 (49%) uncomplicated urogenital gonorrhoea patients receiving BLUJEP A (38% mild severity, 11% moderate severity). Most episodes of diarrhea started on the same day as dosing, with few diarrhea episodes after day 2. The median duration was 2 days. Discontinuation of BLUJEP A due to diarrhea was reported in 1/309 (<1%) uncomplicated urogenital gonorrhoea patients.

Adverse Reactions Occurring in Less than 2% of Uncomplicated Urogenital Gonorrhoea Patients Receiving BLUJEP A in Trial 3:

Skin and Subcutaneous Tissue: Rash

Cardiac Disorders: Tachycardia

Nervous System Disorders: Dysarthria, presyncope, syncope

Musculoskeletal and Connective Tissue Disorders: Muscle spasms, myalgia, arthralgia

Vascular Disorders: Hot flush

Gastrointestinal Disorders: Hypersalivation, abdominal distension

Eye Disorders: Vision blurred

Ear and Labyrinth Disorders: Vertigo

7 DRUG INTERACTIONS

7.1 Effect of Other Drugs on BLUJEPA

CYP3A4 Inhibitors

Table 3. Recommendations for Concomitant Administration of CYP3A4 Inhibitors with BLUJEPA

Indication	Moderate CYP3A4 Inhibitors	Strong CYP3A4 Inhibitors
Uncomplicated UTI	No dosage adjustment	Avoid concomitant administration of BLUJEPA with strong inhibitors of CYP3A4 due to an increase in gepotidacin exposure [see <i>Warnings and Precautions (5.1), Clinical Pharmacology (12.3)</i>].
Uncomplicated Urogenital Gonorrhea	Avoid concomitant administration of BLUJEPA with moderate CYP3A4 inhibitors due to an increase in gepotidacin exposure [see <i>Warnings and Precautions (5.1), Clinical Pharmacology (12.3)</i>].	Avoid concomitant administration of BLUJEPA with strong inhibitors of CYP3A4 due to an increase in gepotidacin exposure [see <i>Warnings and Precautions (5.1), Clinical Pharmacology (12.3)</i>].

CYP3A4 Inducers

Due to decreased gepotidacin exposures, avoid coadministration of BLUJEPA with CYP3A4 inducers as follows:

- Uncomplicated urinary tract infections: Avoid concomitant use of BLUJEPA with strong CYP3A4 inducers [see *Clinical Pharmacology (12.3)*].
- Uncomplicated urogenital gonorrhea: Avoid concomitant use of BLUJEPA with strong and moderate CYP3A4 inducers [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 where minimal concentration changes may lead to serious adverse reactions [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. BLUJEPa may augment the effect of other acetylcholinesterase inhibitors. 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 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 less than the maximum recommended human dose (MRHD). In a mouse pre- and postnatal development study, there were no adverse developmental effects at exposures approximately equal to 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 (less than the MRHD based on AUC extrapolated from nonpregnant rats). Decreased fetal weights and increased late fetal resorptions were seen in mice at oral doses 500 mg/kg/day or greater (less than 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 equal to 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 BLUJEP A and any potential adverse effects on the breastfed child from BLUJEP A 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 maternal exposures as low as 0.2-times the MHRD as extrapolated from exposures in nonpregnant mice).

8.4 Pediatric Use

Uncomplicated UTI

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

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

Uncomplicated Urogenital Gonorrhea

The safety and effectiveness of BLUJEP A for the treatment of uncomplicated urogenital gonorrhea have been established in pediatric patients 12 years of age and older weighing at least 45 kg who have limited or no alternative treatment options [*see*

Indications and Usage (1.1)]. Use of BLUJEP A in these patients is supported by evidence from an adequate and well-controlled study (Trial 3) in adult and pediatric patients with uncomplicated urogenital gonorrhea weighing at least 45 kg, and additional pharmacokinetic analyses showing similar drug exposure levels for pediatric patients (12 to <18 years of age) compared with adults [see *Clinical Pharmacology (12.3)*, *Clinical Studies (14.2)*]. The safety profile of BLUJEP A was similar between pediatric healthy volunteers 12 to <18 years of age (n = 12) who received two 3,000 mg doses compared to adults [see *Adverse Reactions (6.1)*].

The safety and effectiveness of BLUJEP A have not been established for the treatment of uncomplicated urogenital gonorrhea in pediatric patients less than 12 years of age or weighing less than 45 kg.

8.5 Geriatric Use

Uncomplicated UTI

Of the total number of patients who received treatment with BLUJEP A 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 BLUJEP A 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.

BLUJEP A 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)*, *Clinical Pharmacology (12.3)*].

Uncomplicated Urogenital Gonorrhea

Trial 3 did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently from younger subjects.

8.6 Renal Impairment

For Patients with uUTI or Uncomplicated Urogenital Gonorrhea

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 BLUJEP A 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)*, *Clinical Pharmacology (12.3)*].

Additional Recommendations for Patients with Uncomplicated Urogenital Gonorrhea

For patients with uncomplicated urogenital gonorrhea and moderate renal impairment (eGFR 30 to 59 mL/min), avoid use of BLUJEP A when additional risk factors for increased gepotidacin exposure are present [see *Warnings and Precautions (5.1)*].

8.7 Hepatic Impairment

For Patients with uUTI or Uncomplicated Urogenital Gonorrhea

No dosage adjustment is required in patients with mild or moderate hepatic impairment (Child-Pugh Class A/B).

Avoid use of BLUJEP A 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)*, *Clinical Pharmacology (12.3)*].

Additional Recommendations for Patients with Uncomplicated Urogenital Gonorrhea

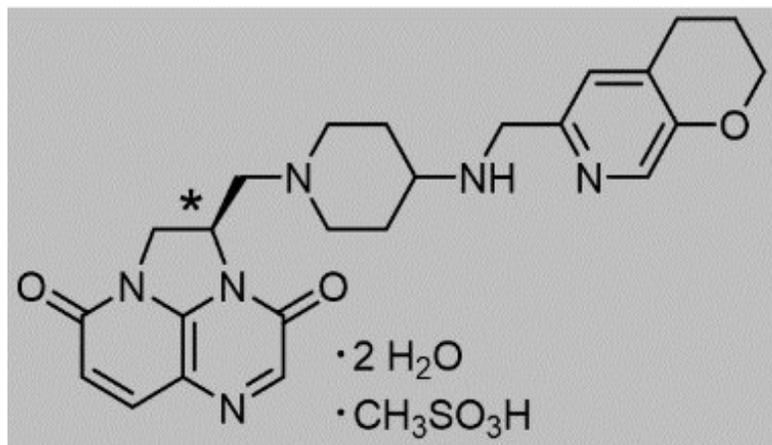
For patients with uncomplicated urogenital gonorrhea and moderate hepatic impairment (Child-Pugh Class B), avoid use of BLUJEP A when additional risk factors for increased gepotidacin exposure are present [see *Warnings and Precautions (5.1)* and *Clinical Pharmacology (12.3)*].

10 OVERDOSAGE

There is a risk of QTc prolongation with overdose. Intermittent hemodialysis is not likely to substantially remove BLUJEP A 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

BLUJEP A 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*-2*a*,5,8*a*-triazacenaphthylene-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 BLUJEP A 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

BLUJEP A 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 1.2 times that of the C_{max} at steady state for the 1,500 mg oral dose twice daily. The C_{max} of gepotidacin following a single 1,800 mg IV dose (not an approved dosing regimen and route of administration) is approximately 1.2 times that of the C_{max} after the second 3,000 mg oral dose given 12 hours after the first oral dose.

12.3 Pharmacokinetics

Pharmacokinetic Parameters

The pharmacokinetic properties of gepotidacin are summarized in Table 4 as mean (standard deviation [SD]) unless otherwise specified.

Table 4. Pharmacokinetic Parameters of Gepotidacin

Dosing Regimen	1,500 mg Every 12 Hours over 5 Days	2 Doses of 3,000 mg 12 Hours Apart
Exposure		
C_{max} (mcg/mL) ^a	6.3 (1.0)	11 (2.7)
AUC (mcg*hour/mL) ^{a,b}	22.8 (4.8)	75.9 (25.9)
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%	

T _{max} (hours)	~2.0	
Effect of food (moderate fat meal) ^c	No clinically significant effect on PK	
Distribution		
V _{ss} (L) ^a	172.9 (42.5)	188.0 (63.7)
Plasma Protein Binding	~25 to ~41%	
Elimination		
Terminal Half-life (hours) ^a	9.3 (1.3)	9.4 (2.3)
Total Clearance (L/hour) ^a	33.4 (6.7)	34.8 (8.7)
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 BLUJEP A 1,500 mg every 12 hours over 5 days, and in simulated results in adults with eGFR greater than or equal to 90 mL/min after oral administration of 2 doses of BLUJEP A (3,000 mg) taken 12 hours apart.

^b AUC₀₋₁₂ at steady state in patients with uUTI; simulated AUC₀₋₂₄ on day 1 in simulated results with uncomplicated urogenital gonorrhoea.

^c Studies evaluating the effect on food were performed with standard and moderate fat meal. Clinical studies were not performed with a high fat meal (1,000 calories, 50% fat).

Specific Populations

Modelling and simulation analyses of gepotidacin showed that age, sex, and race have no clinically relevant effect on gepotidacin exposure. Body weight alone does not result in clinically significant effects 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: Mild hepatic impairment did not have a clinically

relevant effect on gepotidacin pharmacokinetics. Moderate hepatic impairment resulted in an approximately 1.2-fold increase in gepotidacin plasma C_{max} and AUC compared with normal hepatic function. 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 and Model Informed Approaches:

Effect of CYP3A4 Strong 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 BLUJEP A 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 Strong Inducers on the Pharmacokinetics of Gepotidacin: Concomitant administration of BLUJEP A (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 $AUC_{(0-\infty)}$ [see *Drug Interactions (7.1)*].

Effect of BLUJEP A on Pharmacokinetics of Other Drugs: Concomitant administration of a single 0.5 mg dose of digoxin with two 3,000 mg doses of BLUJEP A (an in vitro P-glycoprotein inhibitor), given 12 hours apart (not an approved dosage of BLUJEP A), 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 $AUC_{(0-\infty)}$, and a delayed digoxin T_{max} [see *Drug Interactions (7.2)*].

Concomitant administration of midazolam (2 mg single dose) with BLUJEP A (2 doses of 3,000 mg, given 12 hours apart; not an approved dosage of BLUJEP A) resulted in a 1.9-fold increase in midazolam $AUC_{(0-\infty)}$ [see *Drug Interactions (7.2)*].

Effect of Moderate CYP3A Inhibitors on the Pharmacokinetics of Gepotidacin: Concomitant administration of a moderate CYP3A inhibitor (fluconazole) and single 1,500 mg dose of BLUJEP A is predicted to increase gepotidacin C_{max} by 1.3-fold and AUC by 1.5-fold [see *Drug Interactions (7.1)*].

Effect of Moderate CYP3A Inducers on the Pharmacokinetics of Gepotidacin: Concomitant administration of a moderate CYP3A inducer (efavirenz) and single 1,500 mg dose of BLUJEP A is predicted to decrease AUC and C_{max} by 49% and 34%, respectively [see *Drug Interactions (7.1)*].

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 ($IC_{50}=16.6 \mu M$), and MATE2-K ($IC_{50}=6.9 \mu M$). In vitro, gepotidacin is a substrate of breast cancer resistance protein (max flux rate ratio of 11.0).

12.4 Microbiology

Mechanism of Action

BLUJEP A 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*, 1.2 to 2.7 hours for *E. faecalis*, and 0.7 to 1 hour for *N. gonorrhoeae* 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 (based on *E. coli* numbering) as shown through studies with isogenic mutants in *E. coli* and *K. pneumoniae*. The amino acids GyrA D90, A92 and ParC D86 (based on *N. gonorrhoeae* numbering) as shown through studies with isogenic mutants in *N. gonorrhoeae* may also be important. A single target-specific mutation may not significantly impact gepotidacin activity. In studies of certain amino acid substitutions in GyrA and ParC of *E. coli* and *N. gonorrhoeae*, a direct relationship between gepotidacin and fluoroquinolone susceptibility was not established. However, in a study of isogenic *N. gonorrhoeae* strains with mutations in GyrA S91F, A92T, D95G, and ParC D86N, resistance to both gepotidacin and ciprofloxacin was observed. The clinical significance of these findings is unknown. Gepotidacin activity against *E. coli*, *K. pneumoniae*, and *N. gonorrhoeae* is unrelated to beta-lactam resistance mechanisms.

The frequency of resistance development to gepotidacin due to spontaneous mutations in the gram-negative pathogens 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 Enterobacteriales with ≥ 4 -fold increases in gepotidacin MIC have been identified in vitro and in clinical studies. Using an unapproved single dose of $\leq 3,000$ mg of gepotidacin, three microbiological failures were reported among patients from the Phase 2 clinical study with *N. gonorrhoeae* isolates with a baseline MIC of 1 mcg/mL. Two of these isolates at the end of treatment, had mutations in GyrA and ParC known to be important for gepotidacin binding to the target (ParC D86N, GyrA A92T), and resistance to gepotidacin (MIC increased ≥ 32 -fold). Using 3,000 mg of gepotidacin followed by a second 3,000 mg dose taken approximately 12 hours later, no *N. gonorrhoeae* isolates with gepotidacin MIC values > 2 mcg/mL were observed, including for pre-treatment isolates with a ParC D86N mutation.

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. In vitro activity was also demonstrated against the following *N. gonorrhoeae* MLSTs: ST11422, ST11706, ST1580, ST1583, ST7363, ST7822 and ST9362.

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, or for *N. gonorrhoeae* for gepotidacin in combination with fluoroquinolones, cephalosporins, macrolides, tetracyclines, aminoglycosides, pleuromutilins, and aminocyclitols.

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)*]:

Uncomplicated UTI:

Aerobic bacteria

Gram-positive bacteria

Enterococcus faecalis

Staphylococcus saprophyticus

Gram-negative bacteria

Citrobacter freundii complex

Escherichia coli

Klebsiella pneumoniae

Uncomplicated Urogenital Gonorrhea:

Aerobic bacteria

Gram-negative bacteria

Neisseria gonorrhoeae

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

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 approximately 2 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 approximately 2 and 3 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 uncomplicated urinary tract infections (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 BLUJEP 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 5).

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 United States. Patient demographic and baseline characteristics were generally balanced between treatment groups [see *Adverse Reactions (6.1)*].

Table 5 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 5. 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 6 summarizes the composite response rates at the TOC Visit for the most common baseline uropathogens across both trials in the micro-ITTS population.

Table 6. Composite Response Rates at the Test-of-Cure Visit by Baseline Uropathogen (Trial 1 and Trial 2 Pooled; Micro-ITTS Population)^a

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

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.

14.2 Uncomplicated Urogenital Gonorrhea

A total of 628 patients with suspected uncomplicated urogenital gonorrhea due to *Neisseria gonorrhoeae* were randomized in an open-label, active-controlled, multicenter, multinational trial (Trial 3; NCT04010539). Patients were randomized 1:1 to receive either BLUJEP (3,000 mg taken orally followed by a second dose of 3,000 mg approximately 12 hours later), or a combination of a single intramuscular 500 mg dose of ceftriaxone and single 1 g oral dose of azithromycin.

Patients were eligible for enrollment if they were ≥ 12 years old and >45 kg. Patients with confirmed or suspected complicated or disseminated gonorrhea were excluded from the study. 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 nonsusceptible to ceftriaxone at baseline, consisted of 406 patients (202 for BLUJEP and 204 for ceftriaxone and azithromycin). The demographic and baseline characteristics in the micro-ITT population were comparable between treatment groups. In total, 92% were male; 74% White, 15% Black, 6% Asian, 17% Hispanic or Latino; the mean age was 33 years (range: 17 to 64); the mean weight was 76 kg (range: 48 to 120 kg). 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.

Table 7 shows the primary endpoint of the microbiological success rates at the urogenital site at TOC in the micro-ITT population. Trial 3 demonstrated non-inferiority of BLUJEP to the combination of ceftriaxone and azithromycin.

Table 7. Microbiological Success Rates at the Urogenital Site at TOC, Micro-ITT Population (Trial 3)

	BLUJEP n/N (%)	Ceftriaxone and Azithromycin n/N (%)	Treatment Difference (95% CI)^a
Microbiological success	187/202 (92.6)	186/204 (91.2)	-0.1 (-5.6, 5.5)
Microbiological failure	15/202 (7.4)	18/204 (8.8)	
Bacterial persistence by culture	0	0	
Unable to determine ^b	15/202 (7.4)	18/204 (8.8)	

TOC = Test of Cure; micro-ITT = microbiological Intent to Treat; CI=confidence interval; n = number of patients in subcategory; N = number of patients in the specified population

^a Calculated using Miettinen and Nurminen Summary Score method adjusting for sex and sexual orientation (female, men who have sex with men, or men who have sex with women) for the BLUJEP - (ceftriaxone and azithromycin) treatment difference.

^b Unable to determine outcomes were due to missing data, culture processed beyond 24 hours, TOC out of window, or use of another systemic antimicrobial prior to the TOC visit

16 HOW SUPPLIED/STORAGE AND HANDLING

BLUJEP 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 8 tablets (NDC 0173-0922-38).

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 BLUJEP after a meal to reduce the possibility of gastrointestinal intolerance [see *Dosage and Administration (2.3)*].

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 BLUJEP A can cause dysarthria and other symptoms such as syncope, 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)*, *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 BLUJEP A [see *Warnings and Precautions (5.3)*].

Diarrhea

Counsel patients that diarrhea is a common problem caused by antibacterials, including BLUJEP A. Most reported cases of diarrhea with BLUJEP A were mild to moderate in severity. Diarrhea may occur early in treatment and usually ends when treatment with the antibacterial is discontinued. In most cases, the diarrhea resolved without treatment [see *Warnings and Precautions (5.2)*, *Adverse Reactions (6.1)*].

Sometimes potentially serious diarrhea with 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 BLUJEP A, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When BLUJEP A 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 BLUJEP A 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 BLUJEP A or the effect BLUJEP A may have on other medications, as these may result in decreased effectiveness or increased toxicities of either BLUJEP A 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 BLUJEP A [see *Warnings and Precautions (5.1)*, *Drug Interactions (7)*, *Clinical Pharmacology (12.3)*].

Pregnancy

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

Manufactured for:

GlaxoSmithKline

Durham, NC 27701

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BLJ:3PI

MEDICATION GUIDE
BLUJEP A (blu - JEP - ah)
(gepotidacin)
tablets, for oral use

What is the most important information I should know about BLUJEP A?
BLUJEP A, an antibiotic, can cause serious side effects, including:

- **changes in electrical activity of your heart called QTc prolongation.** BLUJEP A 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 BLUJEP A, 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 BLUJEP A may cause serious side effects. If you are not sure, ask your healthcare provider.
- are taking medicines called moderate or strong CYP3A4 inhibitors. Using these medicines with BLUJEP A 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

- **an increase of a certain chemical in your nervous system (cholinergic effects).** BLUJEP A can cause an increase of a certain chemical in your nervous system, which may cause the following symptoms:

- diarrhea
- vomiting
- nausea
- more saliva in the mouth

- fainting
- trouble saying words clearly
- muscle spasms
- 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 BLUJEP.

The increased chemical in your nervous system 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 BLUJEP including a severe allergic reaction called anaphylaxis. Stop taking BLUJEP 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 BLUJEP. The diarrhea may happen at the beginning of your treatment with BLUJEP and usually stops after the antibiotic is stopped. In most cases the diarrhea will go away without treatment. 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 BLUJEP. 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 BLUJEP?

BLUJEP 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.
- Adults and children 12 years of age and older weighing at least 99 pounds who have very few or no other medicine choices to treat a sexually transmitted disease called uncomplicated urogenital gonorrhea (gonorrhea) caused by a certain type of bacteria.
- It is not known if BLUJEP A is safe and effective for the treatment of uUTI in children under 12 years of age or weighing less than 88 pounds.
- It is not known if BLUJEP A is safe and effective for the treatment of gonorrhea in children under 12 years of age or weighing less than 99 pounds.

Do not take BLUJEP A if:

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

Before taking BLUJEP A, 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 BLUJEP A?”
- 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 BLUJEP A will harm your unborn baby.

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

- **Pregnancy Exposure Registry:** There is a pregnancy exposure registry for women who are exposed to BLUJEP A 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 BLUJEP A, 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 BLUJEP A passes into breast milk. Talk to your healthcare provider about the best way to feed your baby during your treatment with BLUJEP A.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BLUJEP A 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 BLUJEP^a?

- Take BLUJEP^a exactly as your healthcare provider tells you to take it. Check with your healthcare provider if you are not sure.
- The dose of BLUJEP^a for the treatment of uUTI, is 2 tablets by mouth, 2 times each day (about 12 hours apart), for 5 days.
- The dose of BLUJEP^a for the treatment of gonorrhea is 4 tablets taken by mouth followed by a second dose of 4 tablets about 12 hours later.
- Take BLUJEP^a after a meal to decrease the chance of stomach upset.
- For the treatment of uUTI:
 - 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.
- For the treatment of gonorrhea:
 - If you miss a dose, take it as soon as possible.
- If you take too much BLUJEP^a, 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 BLUJEP^a. Do not stop taking BLUJEP^a 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 BLUJEP^a?

BLUJEP^a can cause serious side effects including:

- See “What is the most important information I should know about BLUJEP^a?”

The most common side effects of BLUJEP^a in people with uUTI include:

- | | |
|------------------------------------|----------------------------------------|
| <input type="radio"/> diarrhea | <input type="radio"/> soft stools |
| <input type="radio"/> nausea | <input type="radio"/> dizziness |
| <input type="radio"/> stomach pain | <input type="radio"/> vomiting |
| <input type="radio"/> gas | <input type="radio"/> yeast infections |
| <input type="radio"/> headache | |

The most common side effects of BLUJEP^a in people with gonorrhea include:

- | | |
|------------------------------------|------------------------------------------|
| <input type="radio"/> diarrhea | <input type="radio"/> dizziness |
| <input type="radio"/> nausea | <input type="radio"/> soft stools |
| <input type="radio"/> stomach pain | <input type="radio"/> headache |
| <input type="radio"/> vomiting | <input type="radio"/> feeling tired |
| <input type="radio"/> gas | <input type="radio"/> excessive sweating |

These are not all the possible side effects of BLUJEP^a. 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 BLUJEP^a?

- 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:

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

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GlaxoSmithKline, Durham, NC 27701

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BLJ:2MG

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 12/2025

PRINCIPAL DISPLAY PANEL

NDC 0173-0922-45

BLUJEPA

(gepotidacin)

tablets

750 mg

Rx only

Dispense the accompanying Medication Guide to each patient

20 tablets

GSK

Each tablet contains gepotidacin 750 mg (equivalent to 910.7 mg of gepotidacin mesylate [anhydrous]).

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

Keep out of reach of children.

Do not accept if safety seal under cap is missing or broken.

Recommended Dosage: see Prescribing Information.

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Mft. For: GSK, Durham, NC 27701

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NDC 0173-0922-45
Rx only



BLUJEPA
(gepotidacin)
tablets
750 mg

Dispense the accompanying Medication Guide to each patient



20 tablets

Each tablet contains gepotidacin 750 mg (equivalent to 910.7 mg of gepotidacin mesylate [anhydrous]).
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperature].
Keep out of reach of children.
Do not accept if safety seal under cap is missing or broken.
Recommended Dosage: see Prescribing Information.
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GTIN (01) XXXXXXXXXXXXXXX
EXP YYY-MM
LOT (10) XXXX
S/N (21) XXXXXXXXXXX



BLUJEPA

gepotidacin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0173-0922
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GEPOTIDACIN MESYLATE (UNII: 5P7X0H2O6B) (GEPOTIDACIN - UNII:DVF0PR037D)	GEPOTIDACIN	750 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	G5;GU3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0922-45	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2025	
2	NDC:0173-0922-38	8 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA218230	03/25/2025	

Labeler - GlaxoSmithKline LLC (167380711)