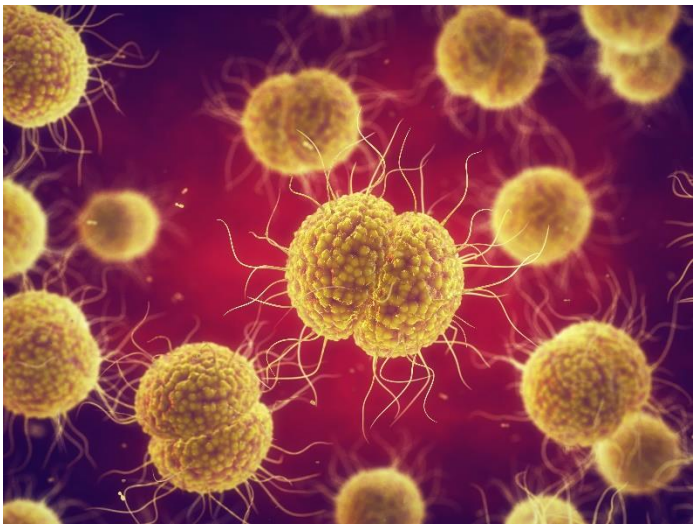
Blujepa From GSK for Uncomplicated Urogenital Gonorrhea

Key Takeaways

- Gepotidacin is approved for treating uncomplicated urogenital gonorrhea in patients aged 12 and older, addressing antimicrobial resistance concerns.
- The antibiotic works by inhibiting bacterial DNA replication through a unique mechanism, effective against resistant strains.
- Clinical trials showed gepotidacin's noninferiority and superiority in some cases compared to existing treatments for gonorrhea.
- Common adverse events include gastrointestinal symptoms; caution is advised with certain medications and patient risk factors.

The FDA approves gepotidacin as a groundbreaking oral treatment for uncomplicated urogenital gonorrhea.

The FDA recently approved gepotidacin (Blujepa; GSK) as an oral treatment for uncomplicated urogenital gonorrhea caused by susceptible strains of Neisseria gonorrhoeae in adults and pediatric patients aged 12 years and older weighing at least 45 kg.1



Gonorrhea is a sexually transmitted infection caused by bacteria and is spread primarily through contact with the genitals or bodily fluids. According to the World Health Organization, in 2020, there were an estimated 82.4 million new infections globally.2,3

Gonorrhea can cause symptoms in the genitals, anus, or throat, typically appearing 1 to 14 days after exposure. Men often develop penile discharge and pain or burning during urination, while some women experience vaginal discharge, painful urination, or irregular bleeding. Many women with gonorrhea do not experience symptoms, causing the infection to be left untreated, which

could lead to infertility and other reproductive health complications.3 Newborns exposed during childbirth can develop eye infections, which can be prevented with routine eye medications.3

The infection is preventable and curable. However, antimicrobial resistance is a growing threat, making antibiotic treatments ineffective and raising concerns that gonorrhea could eventually become untreatable.2,3

Pharmacology and Pharmacokinetics

Gepotidacin is a first-in-class, bactericidal antibiotic that blocks bacterial DNA replication through a unique binding site and a novel mechanism of action. By effectively inhibiting 2 type II topoisomerase enzymes, it works against N gonorrhoeae and key uropathogens such as Escherichia coli and Staphylococcus saprophyticus, including strains resistant to existing antibiotics.1

This new FDA approval comes after gepotidacin was authorized in early 2025 as an oral treatment for uncomplicated urinary tract infection in adult women and in pediatric patients aged 12 and older who were at least 40 kg.4

Dosage and Administration

For uncomplicated urogenital gonorrhea, gepotidacin is given as 3000 mg, or four 750-mg tablets, taken orally, followed by a second 3000-mg dose approximately 12 hours later. The oral treatment should be taken after a meal to reduce gastrointestinal adverse effects.5

Clinical Trials

The FDA approval is based on data from the EAGLE clinical trial program, including the phase 3 EAGLE-1 (NCT04010539),6 EAGLE-2 (NCT04020341),7 and EAGLE-3 (NCT04187144)8 trials.

In EAGLE-1, among the 628 participants, gepotidacin achieved a microbiological success rate of 92.6% compared with 91.2% for ceftriaxone (Rocephin; Roche) plus azithromycin (Zithromax; Pfizer). Additionally, gepotidacin met noninferiority criteria with no persistent urogenital N gonorrhoea detected in either group.9

In EAGLE-2, therapeutic success occurred in 50.6% of patients receiving gepotidacin vs 47% receiving nitrofurantoin (Marcobid; Almatica Pharma LLC); in EAGLE-3, the respective rates were 58.5% and 43.6%. Thus, the study drug demonstrated noninferiority in both studies and superiority in EAGLE-3.9

Contraindications, Warnings, and Precautions

Across trials, diarrhea was the most common adverse event with gepotidacin, followed by nausea, abdominal pain, vomiting, flatulence, dizziness, soft feces, headache, fatigue, and hyperhidrosis.5

Gepotidacin should be avoided in patients taking moderate CYP3A4 inhibitors or with multiple risk factors that increase drug exposure. Additionally, health care providers should monitor acetylcholinesterase-related effects, hypersensitivity reactions, and possible Clostridioides difficile infection.5

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