

For women and girls  $\geq 12$  years with an **uncomplicated UTI**

## How to take BLUJEPA

It's important to take BLUJEPA as prescribed and instructed by your healthcare provider.



**TAKE 2 TABLETS**



**2 TIMES A DAY**

(approximately 12 hours apart)



**FOR 5 DAYS**

after a meal, to reduce the chance of upset stomach



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 many tablets of BLUJEPA, call the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away. If possible, show them the BLUJEPA bottle.

Be sure to take the full course of treatment with BLUJEPA. Do not stop taking BLUJEPA unless directed by your healthcare provider, even if you are feeling better. If you do not complete your full course of treatment, the infection may come back.

### Indication

#### 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.

### IMPORTANT SAFETY INFORMATION

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

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

- **changes in electrical activity of your heart called QTc prolongation.** BLUJEPA can cause QTc prolongation (also called prolonged QTc interval) that can lead to serious heart rhythm problems, including Torsades 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.
- are taking medicines called moderate or strong CYP3A4 inhibitors. 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

**BLUJEPA**   
(gepotidacin) 750 mg tablets

**GSK**

Please see additional Important Safety Information on the next page.

Please see the full **Prescribing Information**, including **Medication Guide**, for BLUJEPA.

## IMPORTANT SAFETY INFORMATION (CONT'D)

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

- diarrhea
- vomiting
- fainting
- 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.

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 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 may happen at the beginning of your treatment with BLUJEPA 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 BLUJEPA. CDI can be life-threatening and can lead to death. Do not take medicines to treat diarrhea without first checking 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

### Who should not take BLUJEPA?

**Do not take BLUJEPA if:**

you have had a severe allergic reaction to 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 (IV) 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 those who are exposed to BLUJEPA during pregnancy. Talk to your healthcare provider about registering with GlaxoSmithKline. You can register by calling 1-888-825-5249.

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 those who are exposed to BLUJEPA during pregnancy. Talk to your healthcare provider about registering with GlaxoSmithKline. You can register by calling 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.

### 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 the FDA at 1-800-FDA-1088.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. You may also report negative side effects to GSK at [gsk.public.reportum.com](http://gsk.public.reportum.com) or 1-888-825-5249.**

**Please see additional Important Safety Information on the previous page.**

**Please see the full [Prescribing Information](#), including [Medication Guide](#), for BLUJEPA.**