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- **Exacerbation of Myasthenia Gravis:** Instruct patients to inform their physician of any history of myasthenia gravis. Instruct patients to notify their physician if they experience any symptoms of muscle weakness, including respiratory difficulties.
- **Hypersensitivity Reactions:** Inform patients that BAXDELA can cause hypersensitivity reactions, even following a single dose, and to discontinue BAXDELA at the first sign of a skin rash, hives or other skin reactions, a rapid heartbeat, difficulty in swallowing or breathing, any swelling suggesting angioedema (for example, swelling of the lips, tongue, face, tightness of the throat, hoarseness), or other symptoms of an allergic reaction.
- **Diarrhea:** Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, instruct patients to contact their physician as soon as possible.
- **Antibacterial Resistance:** Inform patients that antibacterial drugs including BAXDELA Tablets and Injection should only be used to treat bacterial infections. They do not treat viral infections (for example, the common cold). When BAXDELA Tablets and BAXDELA Injection are 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 BAXDELA Tablets and BAXDELA Injection or other antibacterial drugs in the future.

#### Administration with Food and Concomitant Medications

- Inform patients that BAXDELA Tablets may be taken with or without food and without any dietary restrictions [see *Dosage and Administration* (2.1) and *Clinical Pharmacology* (12.3)].
- Inform patients that BAXDELA Tablets should be taken at least 2 hours before or 6 hours after antacids containing magnesium, or aluminum, with sucralfate, with metal cations such as iron, or with multivitamin preparations containing zinc or iron, or with didanosine buffered tablets for oral suspension or the pediatric powder for oral solution.

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**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins and herbal and dietary supplements.

BAXDELA and other medicines can affect each other causing side effects. Especially tell your healthcare provider if you take:

- A steroid medicine. Corticosteroids taken by mouth or by injection may increase the chance of tendon injury. See “What is the most important information I should know about BAXDELA?”
- Certain medicines may keep BAXDELA from working correctly. BAXDELA Tablets should be taken at least 2 hours before or 6 hours after:
  - an antacid, multivitamin, or other product that has magnesium, aluminum, iron, or zinc
  - sucralfate
  - didanosine buffered tablets for oral suspension or the pediatric powder for oral solution

Ask your healthcare provider if you are not sure if any of your medicines are listed above. Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

### **How should I take BAXDELA?**

- Take BAXDELA tablets 2 times a day exactly as your healthcare provider tells you to take it.
- If you have kidney problems, talk with your doctor about how you should take BAXDELA.
- BAXDELA can be taken with or without food.
- BAXDELA IV is given to you by intravenous (IV) infusion into your vein slowly, over 60 minutes, as prescribed by your healthcare provider.
- Do not skip any doses, or stop taking BAXDELA even if you begin to feel better, until you finish your prescribed treatment, unless you have:
  - tendon problems, nerve problems, or central nervous system problems (see “What is the most important information I should know about BAXDELA?”).
  - a serious allergic reaction. See “What are the possible side effects of BAXDELA?”), or your healthcare provider tells you to stop.

Unless you are experiencing any of the harmful side effects listed in this medication guide, take your BAXDELA, as your healthcare provider tells you to take it, to help lower the chance that bacteria will become resistant to BAXDELA. If this happens, BAXDELA and other antibacterial medicines may not work in the future.

- If you miss a dose of BAXDELA, take it as soon as you remember up to 8 hours before your next dose. If you have less than 8 hours before your next dose, wait to take your next dose at your regular time. Do not take more BAXDELA to make up for the missed dose.
- If you take too much BAXDELA, call your healthcare provider or get medical help immediately.

### **What should I avoid while taking BAXDELA?**

BAXDELA can make you feel dizzy and lightheaded. **Do not** drive, operate machinery, or do other activities that require mental alertness or coordination until you know how BAXDELA affects you.

### **What are the possible side effects of BAXDELA?**

BAXDELA may cause serious side effects, including:

- See “What is the most important information I should know about BAXDELA?”
- Serious allergic reactions. Serious allergic reactions, including death, can happen in people taking fluoroquinolones, including BAXDELA, even after only 1 dose. Stop taking BAXDELA and get emergency medical help right away if you get any of the following symptoms of a severe allergic reaction:
  - Hives
  - Swelling of the lips, tongue, face
  - Rapid heartbeat
  - Skin rash
  - Trouble breathing or swallowing
  - Throat tightness, hoarseness
  - Faint

Skin rash may happen in people taking fluoroquinolones even after only 1 dose. Stop taking BAXDELA at the first sign of a skin rash and call your healthcare provider. Skin rash may be a sign of a more serious reaction to BAXDELA.

- **Clostridium difficile-associated diarrhea (CDAD).** CDAD is an infection of your intestines (bowels) that can happen with many antibacterial medicines like BAXDELA and may cause mild diarrhea to life-threatening swelling of your intestines (colitis). Call your healthcare provider right away if you get stomach cramps, fever, watery diarrhea, diarrhea that does not go away, or bloody stools. CDAD can happen 2 or more months after you have finished your antibacterial medicine.

**The most common side effects of BAXDELA include nausea and diarrhea.**

These are not all the possible side effects of BAXDELA. 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 BAXDELA?**

#### **BAXDELA Tablets:**

- Store BAXDELA Tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep BAXDELA away from moisture (humidity).

**Keep BAXDELA and all medicines out of the reach of children.**

### **General information about the safe and effective use of BAXDELA.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BAXDELA for a condition for which it was not prescribed. Do not give BAXDELA 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 BAXDELA that is written for health professionals.

### **What are the ingredients in BAXDELA?**

- **BAXDELA Tablets: 450 mg**  
**Active ingredient:** 450 mg delafloxacin (equivalent to 649 mg delafloxacin meglumine)  
**Inactive ingredients:** Citric acid, Crospovidone, Magnesium stearate, Microcrystalline Cellulose, Povidone, Sodium bicarbonate, and Sodium phosphate monobasic, monohydrate.
- **BAXDELA for Injection: 300 mg**  
**Active ingredient:** delafloxacin  
**Inactive ingredients:** Meglumine, beta-cyclodextrin sulfobutyl ether, and EDTA

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For more information go to [BAXDELA.com](http://BAXDELA.com) or call 1-844-635-4682.

This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised or Issued: June 2017