MEDICATION GUIDE
BREKIYA® [breh-kee-yah]
(dihydroergotamine mesylate)
injection, for subcutaneous use

What is the most important information I should know about BREKIYA?
BREKIYA can cause serious side effects, including:

- **Serious problems with blood circulation to your legs and feet (peripheral ischemia)**. BREKIYA can cause peripheral ischemia when you take it with certain medicines known as CYP3A4 inhibitors. Peripheral ischemia may lead to a stroke and death. Stop taking BREKIYA and get emergency medical help right away if you have any of the following symptoms:
  - cramping and pain in your legs or hips
  - feeling of heaviness or tightness in your leg muscles
  - burning or aching pain in your feet or toes while resting
  - numbness, tingling, or weakness in your legs
  - cold feeling or color changes in 1 or both legs or feet
  - slurred speech
  - sudden weakness

Do not take medicines known as strong CYP3A4 inhibitors, such as:

- ritonavir
- indinavir
- clarithromycin
- itraconazole
- nelfinavir
- erythromycin
- ketoconazole

These are not all of the medicines that could affect how BREKIYA works. Your healthcare provider can tell you if it is safe to take BREKIYA with other medicines.

What is BREKIYA?
BREKIYA is a prescription medicine used for the acute treatment of migraine with or without aura and acute cluster headaches in adults.

- BREKIYA is not used to prevent migraine.
- BREKIYA is not used to treat other types of headaches such as hemiplegic migraines (that make you unable to move on one side of your body) or basilar migraines (rare form of migraine with aura).

It is not known if BREKIYA is safe and effective in children.

Who should not take BREKIYA? Do not use BREKIYA if you:

- are taking medicines known as strong CYP3A4 inhibitors.
- have heart problems or a history of heart problems.
- have uncontrolled high blood pressure.
- have narrowing of blood vessels in your legs, arms, stomach, or kidneys (peripheral vascular disease).
- have sepsis.
- have had vascular surgery.
- have severe liver problems.
- have severe kidney problems.
- are allergic to dihydroergotamine, ergot alkaloids, latex, or any of the ingredients in BREKIYA. See the end of this Medication Guide for a complete list of ingredients in BREKIYA.
- have taken any of the following medicines in the last 24 hours:
  - sumatriptan
  - almotriptan
  - eletriptan
  - frovatriptan
  - naratriptan
  - rizatriptan
  - ergotamine or ergotamine-type medicines
  - zolmitriptan
- have taken any medicines that constrict your blood vessels or raise your blood pressure.

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take BREKIYA with other medicines.

Before you take BREKIYA, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure.
- have liver problems.
- have kidney problems.
- have risk factors for heart disease. You have a higher risk for heart disease if you:
  - have high blood pressure
  - have high cholesterol levels
  - smoke
  - are overweight
  - have diabetes
  - have a family history of heart disease
- are taking medicines known as strong CYP3A4 inhibitors.

- are pregnant or plan to become pregnant. BREKIYA may cause preterm labor. BREKIYA should be avoided during pregnancy. Talk to your healthcare provider right away if you are pregnant or want to become pregnant.
- are breastfeeding or plan to breastfeed. BREKIYA may reduce breast milk supply and pass into your breast milk. BREKIYA may be harmful to your baby. Do not breastfeed your baby while taking BREKIYA and for 3 days after you use BREKIYA. Talk with your healthcare provider about the best way to feed your baby if you take BREKIYA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider will decide if you can take BREKIYA with your other medicines.

Especially tell your healthcare provider if you take:

- sumatriptan
- ergot-type medicine
- saquinavir
- nefazodone
- fluconazole
- grapefruit juice
- zileuton
- nicotine
- propranolol or other medicines that can lower your heart rate
- any medicines that can increase your blood pressure
- selective serotonin reuptake inhibitors

These are not all of the medicines that could affect how BREKIYA works. Your healthcare provider can tell you if it is safe to take BREKIYA with other medicines.

How should I use BREKIYA?

- Certain people should take their first dose of BREKIYA in their healthcare provider's office or in another medical setting. Ask your healthcare provider if you should take your first dose in a medical setting.
- BREKIYA is for injection under the skin (subcutaneous) only.
- Use BREKIYA exactly as your healthcare provider tells you to use it.
- See the detailed Instructions for Use that comes with BREKIYA for information about how to use BREKIYA.
- Each autoinjector contains 1 dose (1 mg) of BREKIYA.
- If your headache comes back after the first complete dose, you may give yourself up to 2 more doses as needed. Wait at least 1 hour between doses.
- **Do not** inject more than 3 doses (3 mg) of BREKIYA in a 24-hour period or 6 doses (6 mg) in a 1-week (7 day) period.
- Using BREKIYA for 10 or more days in 1 month may make your headache worse. You should write down when you have headaches and when you take BREKIYA so that you can talk with your healthcare provider about how BREKIYA is working for you.
- If you use too much BREKIYA, call your healthcare provider or the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of BREKIYA?

BREKIYA can cause serious side effects, including:

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

- **Heart attack and other heart problems.** Heart problems may lead to death. Stop taking BREKIYA and get emergency medical help right away if you have any of the following symptoms of a heart attack:
  - discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
  - severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
  - pain or discomfort in your arms, back, neck, jaw, or stomach
  - shortness of breath with or without chest discomfort
  - breaking out in a cold sweat
  - nausea or vomiting
  - feeling lightheaded

  BREKIYA is not for people with risk factors for heart disease unless a heart exam is done and shows no problem. See **"Before you take BREKIYA, tell your healthcare provider about all of your medical conditions, including if you:"** for the risk factors for heart disease.
- **Stroke.** Stop using BREKIYA and get emergency medical help right away if you have any of the following symptoms of a stroke:
  - face drooping
  - unusual weakness or numbness
  - slurred speech
- **Changes in color or sensation in your fingers and toes (Raynaud's syndrome).**
- **Stomach and intestinal problems** (gastrointestinal and colonic ischemic events). Symptoms of gastrointestinal and colonic ischemic events include:
  - sudden or severe stomach pain
  - bloody diarrhea
  - nausea or vomiting
  - constipation or diarrhea
  - weight loss
  - stomach pain after meals
  - fever
- **Increased blood pressure.**
- **Medicine overuse headache.** Some people who use too much BREKIYA may make their headaches worse (medicine overuse headache). If your headaches get worse, your healthcare provider may decide to stop your

treatment with BREKIYA.

- **Preterm labor.**
- **Tissue changes (fibrotic complications).** Inflammation and fiber-like tissue that is not normal (fibrosis) can occur around the lungs and stomach.

The most common but serious side effects of BREKIYA are heart problems that happen but may lead to death. These heart problems include:

- temporary squeezing of arteries that supply the heart (coronary artery vasospasm)
- temporary decrease of blood flow to the heart (transient myocardial ischemia)
- heart rhythm problems (ventricular tachycardia and ventricular fibrillation)

Symptoms of these heart problems include:
See "**heart attack and other heart problems**."

- numbness or tingling in your fingers and toes.
- muscle pain or cramps in your arms and legs.
- weakness in your legs.
- temporary speeding or slowing of your heart rate.
- swelling or itching.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of BREKIYA. 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 BREKIYA?

- Store BREKIYA at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not refrigerate or freeze BREKIYA.
- Protect BREKIYA from light.
- Keep BREKIYA in the original pack until ready to use.

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

General information about the safe and effective use of BREKIYA.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BREKIYA for a condition for which it was not prescribed. Do not give BREKIYA to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BREKIYA that is written for health professionals.

What are the ingredients in BREKIYA?
Active ingredient: dihydroergotamine mesylate, USP
Inactive ingredients: ethanol, glycerin, water for injection, methanesulfonic acid or sodium hydroxide.

Distributed by:
Amneal Specialty, a division of Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

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Amneal Pharmaceuticals Pvt. Ltd.
Ahmedabad 382213, INDIA

For more information or to report side-effects, call 1-877-835-5472.

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