

MEDICATION GUIDE
ARIKAYCE (ar' i kase) LIMITED POPULATION
(amikacin liposome inhalation suspension)
for oral inhalation use

Important: For oral inhalation only.

What is the most important information I should know about ARIKAYCE?

ARIKAYCE can cause serious side effects, including:

- **allergic inflammation of the lungs:** These respiratory problems may be symptoms of allergic inflammation of the lungs and often come with:
 - fever
 - coughing
 - fast breathing
 - wheezing
 - shortness of breath
- **coughing up of blood (hemoptysis):** Coughing up blood is a serious and common side effect of ARIKAYCE.
- **severe breathing problems:** Severe breathing problems can be symptoms of bronchospasm. Bronchospasm is a serious and common side effect of ARIKAYCE. Bronchospasm symptoms include:
 - shortness of breath
 - wheezing
 - difficult or labored breathing
 - coughing or chest tightness
- **worsening of chronic obstructive pulmonary disease (COPD):** This is a serious and common side effect of ARIKAYCE.
- **serious allergic reactions:** Serious allergic reactions that may lead to death have happened to people who take ARIKAYCE. Stop taking ARIKAYCE right away and get emergency medical help if you have any of the following symptoms of a serious allergic reaction:
 - hives
 - itching
 - redness or blushing of the skin (flushing)
 - swollen lips, tongue or throat
 - trouble breathing or wheezing
 - shortness of breath
 - noisy high-pitched breathing (stridor)
 - cough
 - nausea
 - vomiting
 - diarrhea
 - feel cramps in your stomach area
 - fast heart rate
 - feeling light headed
 - feeling faint
 - loss of control of the bowels or bladder (incontinence)
 - dizziness

While using ARIKAYCE these side effects may become serious enough that treatment in a hospital is needed.

Call your healthcare provider or get medical help right away if you have any of these serious side effects while taking ARIKAYCE. Your healthcare provider may ask you to stop using ARIKAYCE for a short period of time or completely stop using ARIKAYCE.

What is ARIKAYCE?

ARIKAYCE is a prescription medicine used to treat adults with refractory (difficult to treat) *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug treatment plan (regimen).

It is not known if ARIKAYCE is safe and effective in children younger than 18 years of age.

This product was approved by FDA using the Limited Population pathway. This means FDA has approved this drug for a limited and specific patient population, and studies on the drug may have only answered focused questions about its safety and effectiveness.

Do not use ARIKAYCE if you:

- are allergic to any aminoglycoside, or any of the ingredients in ARIKAYCE. See **“What are the ingredients in ARIKAYCE?”** at the end of this leaflet for a complete list of ingredients in ARIKAYCE.

Before using ARIKAYCE, tell your healthcare provider about all of your medical conditions, including if you:

- have asthma, chronic obstructive pulmonary disease (COPD), shortness of breath or wheezing (bronchospasm).
- have been told you have poor lung function.
- have or have had hearing problems (including noises in your ears such as ringing or hissing), hearing loss, or your mother has had hearing problems after taking an aminoglycoside.
- have been told you have certain gene variants (a change in the gene) related to hearing abnormalities inherited from your mother.
- have dizziness or sense of the room spinning.
- have kidney problems.
- have neuromuscular disease such as myasthenia gravis.
- are pregnant or plan to become pregnant. It is not known if ARIKAYCE can harm your unborn baby. ARIKAYCE is in a class of medicines that may be connected with complete deafness in babies at birth. The deafness affects both ears and cannot be changed.
- are breastfeeding or plan to breastfeed. It is not known if the medicine in ARIKAYCE passes into your breast milk and if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with ARIKAYCE.

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

How should I use ARIKAYCE?

- **Read the step-by-step instructions for using ARIKAYCE at the end of the Medication Guide and the full Instructions for Use provided in your kit.** The manufacturer's Instructions for Use provides complete information about how to put together (assemble), prepare, use, clean, and disinfect your Lamira® Nebulizer System.
- **Do not** use ARIKAYCE unless you understand the directions provided. If you have questions talk to your health care provider or call Arikares Support at 1-833-ARIKARE (1-833-274-5273).
- Use ARIKAYCE exactly as your healthcare provider tells you to use it. Do not use ARIKAYCE more often than prescribed for you.
- Only use ARIKAYCE with the Lamira Nebulizer System.
- Inhale each daily dose of ARIKAYCE 1 time each day through the Lamira Nebulizer Handset. **Do not** use more than 1 vial of ARIKAYCE in a day.
- Do not use ARIKAYCE after the expiration date on the vial. If you forget to take your daily dose of ARIKAYCE, take your next dose at your usual time the next day.
- **Do not** double the dose to make up for the missed dose.
- **Do not** stop using ARIKAYCE or other medicines to treat your MAC lung disease unless told to do so by your healthcare provider.
- If you use too much ARIKAYCE, call your healthcare provider or go to the nearest emergency room right away.

What are the possible side effects of ARIKAYCE?

ARIKAYCE may cause serious side effects, including:

- **See “What is the most important information I should know about ARIKAYCE?”**
- **hearing loss or ringing in the ears (ototoxicity).** Ototoxicity is a serious and common side effect of ARIKAYCE. Tell your healthcare provider right away if you have hearing loss or you hear noises in your ears such as ringing or hissing. Tell your healthcare provider if you start having problems with balance or dizziness (vertigo).
- **worsening kidney problems (nephrotoxicity).** ARIKAYCE is in a class of medicines which may cause worsening kidney problems. Your healthcare provider may do a blood test to check how well your kidneys are working during your treatment with ARIKAYCE.
- **worsening muscle weakness (neuromuscular blockade).** ARIKAYCE is in a class of medicines which can cause muscle weakness to get worse in people who already have problems with muscle weakness (myasthenia gravis).

The most common side effects of ARIKAYCE include:

- changes in your voice and hoarseness (dysphonia)
- tiredness (fatigue)
- headache
- rash
- cough during or after a dose of ARIKAYCE, especially in the first month after starting treatment.
- sore throat
- diarrhea
- fever
- decreased weight
- chest discomfort
- muscle pain
- nausea
- vomiting
- increased sputum

These are not all of the possible side effects of ARIKAYCE.

Call your doctor or pharmacist for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

How should I store ARIKAYCE?

- Store ARIKAYCE vials refrigerated between 36°F to 46°F (2°C to 8°C) until the expiration date on the vial. Do not freeze.
- After ARIKAYCE has been stored in the refrigerator, any unused medicine must be thrown away (disposed of) after the expiration date on the vial.
- Store ARIKAYCE vials at room temperature between 68°F to 77°F (20°C to 25°C) for up to 4 weeks
- After ARIKAYCE has been stored at room temperature any unused medicine must be thrown away (disposed of) at the end of 4 weeks.
- Use an opened ARIKAYCE vial right away.
- Throw away the ARIKAYCE vial right away after use.

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

General information about safe and effective use of ARIKAYCE

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

What are the ingredients in ARIKAYCE?

Active ingredient: amikacin sulfate

Inactive ingredients: Dipalmitoylphosphatidylcholine (DPPC), cholesterol, sodium chloride, sodium hydroxide (for pH adjustment), and water for injection

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For more information, call Insmed Arikare Support at: 1- 833-ARIKARE (1-833-274-5273)

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

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