



Limited Population

What to expect from treatment with ARIKAYCE

You're about to take the next step of your treatment journey with ARIKAYCE—the **first and only FDA-approved treatment option** designed specifically for *Mycobacterium avium* complex (MAC) lung disease as part of a multidrug treatment plan in adults who continue to test positive after at least 6 months of a multidrug regimen alone.

Everyone responds to treatment differently. That's why, before starting treatment, it's important that you and your doctor work together to come up with a treatment plan that works for you.



Discuss with your doctor how long you will be taking ARIKAYCE, so you can feel more prepared for your treatment journey



Make a plan for fitting ARIKAYCE into your routine—determine when and where you will be most comfortable taking your treatment



Keep track of any side effects you experience, and ask your doctor about any techniques you can try to help manage them

If you do experience any side effects while taking ARIKAYCE, be sure to talk to your doctor.

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.

IMPORTANT SAFETY INFORMATION

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, wheezing, coughing, shortness of breath, and fast breathing
- **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, difficult or labored breathing, wheezing, and coughing or chest tightness

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.

Scan this code to hear stories from real patients about their experiences taking ARIKAYCE.



In a clinical study, patients on ARIKAYCE tested MAC-negative, even after completing treatment



- ARIKAYCE helped **3X*** as many patients test MAC-negative at 6 months (65/224 vs 10/112)
- ARIKAYCE helped **7X*** as many patients test MAC-negative at 12 months (41/224 vs 3/112)
- **Only** ARIKAYCE patients tested MAC-negative 3 months after completing treatment (36/224 vs 0/112)

Learn more at [ARIKAYCE.com](https://www.arikeyce.com) or use this code to download the ARIKAYCE Brochure.



Knowing the possible side effects of ARIKAYCE

While these are not all of the possible side effects, below are some of the side effects associated with ARIKAYCE in the study.

- The most serious side effects were hearing loss or ringing in the ears (ototoxicity), worsening kidney problems (nephrotoxicity), and worsening muscle weakness (neuromuscular blockade)
- The most common side effects of ARIKAYCE were changes in your voice, hoarseness, cough during or after a dose of ARIKAYCE, muscle pain, sore throat, fatigue, diarrhea, nausea, headache, fever, decreased weight, vomiting, rash, increased sputum, and chest discomfort

81%

Most patients who experienced side effects did not stop treatment

81% (182/224) of patients taking ARIKAYCE + multidrug regimen did not stop treatment even though they had at least one side effect

Fortunately, there are things you can do to help prepare for and manage potential side effects. Talk to your doctor about any side effects you may experience and ways to help address them.

*Percentage comparison.

IMPORTANT SAFETY INFORMATION (cont'd)

- **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), and dizziness

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Managing potential side effects along your ARIKAYCE treatment journey

Below are the potential techniques and strategies used in a 2019 survey to help manage certain respiratory-related side effects when taking ARIKAYCE. The survey was conducted via telephone with 26 patients prescribed ARIKAYCE during a 2-month period at 2 academic medical centers in the United States.

Management strategy	Increased coughing	Changes in voice and hoarseness (dysphonia)	Shortness of breath (dyspnea)	Increased sputum production
Lozenges	•	•		
Soothing fluid intake	•	•		
Warm water or glycerin gargle postdosing	•	•		
Limiting physical activity			•	
Changing ARIKAYCE administration to evening	•	•		
Brief interruptions of ARIKAYCE	•	•	•	
Bronchodilator use (medicine that increases airflow to the lungs)	•		•	
Antitussive agents (cough medicine)	•	•		
Increased supplemental oxygen, if already administering			•	
Airway clearance [†] (eg, specific breathing techniques, chest percussion, and positive expiratory pressure therapy)				•

[†]Increased sputum production may be a form of airway clearance in itself.

Survey disclosures

- This information is not included in the ARIKAYCE full Prescribing Information
- Writing assistance was provided to the authors through funding from Insmid Incorporated
- Insmid was not involved with the conceptualization, development, conduct, or analyses of the study

Remember, you and your doctor should always work together through any treatment challenges you experience. Use this section for notes from your conversation:



IMPORTANT SAFETY INFORMATION (cont'd)

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.

Do not use ARIKAYCE if you are allergic to any aminoglycoside, or any of the ingredients in ARIKAYCE.

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

- have asthma, COPD, shortness of breath, or wheezing (bronchospasm)
- have been told you have poor lung function
- have hearing problems, such as ringing in your ears or hearing loss
- have dizziness or a 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.

ARIKAYCE may cause serious side effects, including:

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

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 or www.fda.gov/medwatch.**

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.