



## Testing positive for MAC despite treatment? Talk to your doctor about what's next.

**MAC lung disease is tough, and can take time to treat and manage.** That's why it's important to talk to your doctor about your long-term treatment plan, including what you may experience along the way.

The goal of treatment for MAC lung disease is to test MAC-negative because testing positive for MAC may put you at risk for permanent lung damage even if you're feeling better.

### If you're still testing positive for MAC, you have options

While a multidrug treatment works for most people, some may find it's simply not enough to test MAC-negative. That's where ARIKAYCE comes in.

ARIKAYCE is different because the antibiotic is contained inside tiny particles called liposomes that are designed to target the MAC infection directly in the lungs.

In a clinical study, adding ARIKAYCE to a multidrug treatment helped 29% (65/224) of people with difficult-to-treat MAC lung disease test MAC-negative at 6 months compared to 8.9% (10/112) of people on a multidrug treatment alone. After 6 months, people on ARIKAYCE did not see an improvement in their 6-minute walk test and St George's Respiratory Questionnaire measurements.

ARIKAYCE is the **first and only FDA-approved treatment** used in combination with multidrug therapy for adults who still test positive for MAC after at least 6 months on multidrug treatment alone.

ARIKAYCE 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.



### Treatment experts strongly recommend adding ARIKAYCE

The NTM Treatment Guidelines\* recommend adding ARIKAYCE in combination with your multidrug treatment if you're still testing positive for MAC after 6 months.

\*ATS/ERS/ESCMID/IDSA NTM guidelines.

ATS=American Thoracic Society; ERS=European Respiratory Society; ESCMID=European Society of Clinical Microbiology and Infectious Diseases; IDSA=Infectious Diseases Society of America; MAC=*Mycobacterium avium* complex; NTM=nontuberculous mycobacteria.

Ready to talk to your doctor about ARIKAYCE?  
**Start the conversation**



### IMPORTANT SAFETY INFORMATION AND BOXED WARNING

**ARIKAYCE is associated with a risk of increased respiratory adverse reactions including allergic inflammation of lungs, coughing up blood, severe breathing problems and worsening of COPD.**

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including Boxed Warning, at [ARIKAYCE.com](#).

  
**ARIKAYCE**<sup>®</sup>  
(amikacin liposome  
inhalation suspension)  
**Limited Population**

# Questions to ask your doctor about ARIKAYCE

Use these questions as a guide to help prepare for your next doctor's visit and make the most of your time together.

## About ARIKAYCE

- ☐ How do we decide if adding ARIKAYCE is right for me?
- ☐ How does ARIKAYCE work?
- ☐ What does the data say? Could ARIKAYCE help me test MAC-negative?
- ☐ What are the potential side effects of ARIKAYCE, and is there anything I can do if I experience any?

## Starting ARIKAYCE

- ☐ How is ARIKAYCE taken and how often?
- ☐ What is the goal of treatment?
- ☐ Is there support to help me get started on ARIKAYCE?



### Is adding ARIKAYCE right for you? Make sure your doctor has all the facts

It's important to help your doctor make the best decisions about your care by informing them:

- How long you've been taking your current multidrug treatment
- How long you've been testing positive for MAC while on treatment
- How you are responding to treatment so far and if you're ready to learn about other options like ARIKAYCE

ARIKAYCE is used in combination with multidrug therapy for adults who still test positive for MAC lung disease after at least 6 months on multidrug therapy alone.

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## IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

### 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
- **worsening of chronic obstructive pulmonary disease (COPD).** This is a serious and common side effect of ARIKAYCE

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## Notes

### IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

#### ARIKAYCE can cause serious side effects, including: (cont'd)

- **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

**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

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**Before using ARIKAYCE, tell your healthcare provider about all medical conditions, including if you: (cont'd)**

- 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](http://www.fda.gov/medwatch).**

## WHAT IS ARIKAYCE?

ARIKAYCE is used in combination with multidrug therapy for adults who still test positive for MAC lung disease after at least 6 months on multidrug treatment alone.

ARIKAYCE 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.

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

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