



**ARIKAYCE**<sup>®</sup>  
(amikacin liposome  
inhalation suspension)  
590 mg/8.4 mL

**Limited  
Population**

# ARIKAYCE

The first and only FDA-approved medication for the treatment of refractory (difficult to treat) **MAC lung disease** as part of a combination antibacterial drug treatment plan

MAC=*Mycobacterium avium* complex.

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.

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

## **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)** is a serious and common side effect of ARIKAYCE
- **severe breathing problems** can be symptoms of bronchospasm, which is a serious and common side effect of ARIKAYCE. Symptoms include shortness of breath, difficult or labored breathing, wheezing, and coughing or chest tightness
- **worsening of chronic obstructive pulmonary disease (COPD)** is a serious and common side effect of ARIKAYCE

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

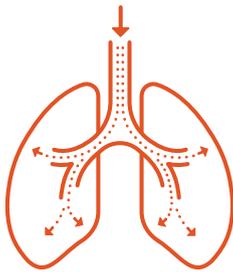
**Please see additional Important Safety Information on pages 7-9 and enclosed full Prescribing Information.**

# What is ARIKAYCE?

ARIKAYCE (amikacin liposome inhalation suspension) is a prescription medicine used to treat people with refractory (difficult to treat) MAC lung disease. It is an inhaled, liposomal form of the antibiotic amikacin. ARIKAYCE is used as part of a combination antibacterial drug treatment plan.

In ARIKAYCE, the amikacin is contained inside tiny particles called liposomes. These liposomes are designed to help the medicine reach the lungs.

When you inhale ARIKAYCE, the liposomes containing the medicine travel into your lungs. There, they enter the body's cells, called macrophages, where the MAC bacteria can live.



To learn more, visit

[ARIKAYCE.com/about](https://www.arikeyce.com/about)

## IMPORTANT SAFETY INFORMATION (cont'd)

**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.

# ARIKAYCE is designed to be taken with the Lamira Nebulizer System

- ARIKAYCE should only be used with the Lamira™ Nebulizer System, and should be taken once daily
- At the start of your treatment, you will receive 2 shipments from a specialty pharmacy. One includes a 28-day supply of ARIKAYCE; the other includes a one-time shipment of the Lamira Nebulizer System
- Going forward, you will receive monthly shipments of a 28-day supply of ARIKAYCE



To watch a step-by-step video on taking ARIKAYCE, visit

[ARIKAYCE.com/instructions](https://www.arikeyce.com/instructions)

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\*See the full Prescribing Information for ARIKAYCE for information about the limited population.

  
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## A look at the ARIKAYCE study



ARIKAYCE + combination antibacterial drug treatment plan was studied in **224 adult patients** who had been diagnosed with MAC lung disease.



In order to participate in this study, all of the patients had **previously been treated** with a combination antibacterial drug treatment alone. And **they did not respond to treatment**.

To find out more, visit

[ARIKAYCE.com/about](https://www.arikeyce.com/about)

### IMPORTANT SAFETY INFORMATION (cont'd)

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

## Results from the ARIKAYCE study

### 3X AS MANY PEOPLE TESTED NEGATIVE

ARIKAYCE +  
COMBINATION  
ANTIBACTERIAL  
DRUG TREATMENT  
PLAN  
65 OUT OF 224  
PEOPLE



VS



COMBINATION  
ANTIBACTERIAL  
DRUG TREATMENT  
ALONE  
10 OUT OF 112  
PEOPLE

**3X as many people tested negative for MAC lung disease** 6 months after being on ARIKAYCE + combination antibacterial drug treatment plan vs those on a combination antibacterial drug treatment alone.

**27.7%**  
VS  
**6.3%**

Among **all patients in the study**, 27.7% (62/224) of patients on ARIKAYCE + combination antibacterial drug treatment plan still tested negative for MAC lung disease after 6 months. This was compared to 6.3% (7/112) of patients on combination antibacterial drug treatment alone after 6 months.

**95.4%**  
VS  
**70%**

Among the **patients who tested negative** for MAC lung disease during the study, 95.4% (62/65) of people taking ARIKAYCE + combination antibacterial drug treatment plan still tested negative for MAC lung disease after 6 months. This was compared to 70% (7/10) of the people taking the combination antibacterial drug treatment alone, who still tested negative for MAC lung disease after 6 months.

To find out if ARIKAYCE is right for you,

[talk to your doctor](#)

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## Arikares support is available

The Arikares™ Support Program is here to provide you with important information and ongoing support throughout your treatment journey.



The Arikares Support Program is designed to help you get started on ARIKAYCE® (amikacin liposome inhalation suspension) and become familiar with how to use your device. Additionally, the program provides assistance with insurance coverage and information on financial support options for eligible patients.

For more information on the Arikares Support Program, and to download an enrollment form to bring to your doctor's office, visit

[ARIKAYCE.com/support](https://www.arikeyce.com/support)

### Savings and financial support

Insmed is committed to providing access to ARIKAYCE. To learn more about potential savings and financial support options, Arikares Coordinators are available to answer your questions at **1-833-ARIKARE (1-833-274-5273)**.

For any questions about savings or financial support, visit

[ARIKAYCE.com/savings](https://www.arikeyce.com/savings)

**Arikares™**

## INDICATION AND IMPORTANT SAFETY INFORMATION

### 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.

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

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).**

To find out more, visit

[ARIKAYCE.com](http://ARIKAYCE.com)

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# What is MAC lung disease?

*Mycobacterium avium* complex (MAC) is the most common form of nontuberculous mycobacteria (NTM). NTM are bacteria commonly found in the environment.

## Who is at risk for MAC lung disease?

MAC lung disease can get inside your lungs when you breathe them in, and can affect certain people more than others. Most people who come in contact with MAC do not develop an infection.

However, people are more likely to develop MAC lung disease if they have a history of lung conditions, such as:

- Bronchiectasis
- COPD
- Asthma



If you think you might have MAC lung disease,

**talk to your doctor**

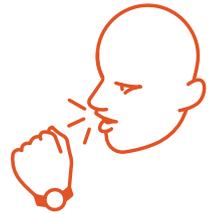
Additionally, MAC lung disease most commonly affects people who are:

- Women
- Aged 65 and older
- Have weakened immune systems
- Live in coastal areas



## What are the main symptoms of MAC lung disease?

- Coughing
- Feeling tired
- Shortness of breath



These symptoms often get worse over time and tend to not go away.

Learn more about MAC at

**ARIKAYCE.com/mac**

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# Start a conversation with your doctor about ARIKAYCE



The Doctor Discussion Guide is a useful resource with a list of important questions to ask your doctor, as well as tips on how to make the most of your next appointment.

Download the Doctor Discussion Guide at

**ARIKAYCE.com**

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## **IMPORTANT SAFETY INFORMATION (cont'd)**

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

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