



What you may
experience
through your

MAC
treatment
journey


ARIKAYCE[®]
(amikacin liposome
inhalation suspension)

Limited Population

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 enclosed full Prescribing Information, including Boxed Warning.



Learn more about ARIKAYCE for MAC lung disease

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (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.**

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What you may experience through your **MAC** treatment journey



STARTING TREATMENT

Your treatment goal

MAC lung disease is tough and **can take time to treat and manage**; that's why it's important to partner with your doctor, keep the lines of communication open, and establish a treatment plan.

The goal of treatment is to get rid of MAC bacteria (what's known as "culture conversion" or testing MAC-negative) because MAC lung disease may put you at risk for permanent lung damage.

Guidelines recommend **staying on treatment for at least 12 months** after you test negative for MAC lung disease.



You're prescribed a multidrug treatment

Treating MAC lung disease initially involves multiple oral antibiotics.

Treatment guidelines recommend getting **sputum (mucus) tests every few months** to help you know whether or not you are testing MAC-negative.

Your treatment may be reevaluated if you aren't testing MAC-negative **after 6 months**.

Certain breathing exercises and airway clearance techniques may also be recommended to help clear out mucus.



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

Multidrug treatment works for most people. However, some may find it is simply not enough to test MAC-negative. Their treatment may either change or be added to, as a result.

ONGOING TREATMENT

STILL TESTING POSITIVE FOR MAC AFTER 6 MONTHS

It may be time to add ARIKAYCE

ARIKAYCE is the first and only FDA-approved treatment 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.



An inhaled antibiotic taken with a nebulizer



Designed to target the MAC infection directly in the lungs



Proven to help people test and stay MAC-negative

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.

With ARIKAYCE, consider:

- Establishing a routine that helps you nebulize **once a day**
- Tracking your progress throughout treatment
- Talking to your doctor about possible side effects and ways to help manage them



Discover strategies to manage side effects

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.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING

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

Get support throughout your treatment journey

The Arikares® Support Program provides a team to help you throughout your ARIKAYCE treatment, including 1:1 support with your Arikares Coordinator as you start your treatment.

For more information, call **1-833-ARIKARE (1-833-274-5273)** or 1-973-437-2376.



Arikares®
Support Program

Explore all that the program has to offer

MAC lung disease is tough and can take time to treat and manage

That's why it's important to keep the lines of communication open, and establish a treatment plan.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (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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3 things to know when starting your MAC treatment journey



The goal of
treatment is to test
MAC-negative.
It may take
some time



Initial treatment
usually starts
with multiple
oral antibiotics



Treatment
guidelines strongly
recommend
adding ARIKAYCE
if you're
still testing
positive after at
least 6 months
on your multidrug
treatment

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