THE FIRST AND ONLY FDA-APPROVED TREATMENT OPTION FOR REFRACTORY* MAC LUNG DISEASE

ARIKAYCE®
(amikacin liposome inhalation suspension)

Limited Population

Treatment experts strongly recommend adding ARIKAYCE

The NTM Treatment Guidelines,† created by leading scientific communities, recommend adding ARIKAYCE, the first and only FDA-approved treatment for adults who still test positive for *Mycobacterium avium* complex (MAC) after 6 months on an initial multidrug treatment.

The NTM Treatment Guidelines recommend:

When MAC is diagnosed: Start a multidrug treatment

The guidelines suggest beginning treatment rather than waiting, especially for those with:

- **a more severe infection**
- **a compromised immune system**
- **severe fatigue or other signs of decreased quality of life**
- **cavitary disease**

Treating MAC lung disease involves taking more than 1 medication. These medications work together to fight the MAC bacteria.

During Months 1–5 of treatment: Frequent sputum tests

The guidelines recommend regular doctor visits and monthly sputum cultures to assess if a person is responding to therapy.

6 months after start of treatment: Test MAC-negative?

The guidelines recommend that doctors evaluate if the multidrug treatment is working after 6 months.

NO. Still MAC-positive

Treatment guidelines strongly recommend adding ARIKAYCE when continuing to test positive after 6 months of treatment

ARIKAYCE was approved by FDA using the Limited Population pathway for a limited and specific patient population.

YES. Tested MAC-negative

Continue multidrug treatment.

Additional recommendation: Continue on treatment for 12 months after testing MAC-negative

The guidelines recommend staying on NTM treatment for a minimum of 12 months after testing negative for MAC. This is to help make sure MAC bacteria is cleared from your lungs.

*Refractory MAC lung disease is defined as MAC patients who did not convert after ≥6 months of standard therapy.
†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.

Learn about adding the **first and only FDA-approved treatment** for adults who still test positive for MAC lung disease after 6 months on an initial multidrug treatment. **See the positive side of negativity.**

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.

IMPORTANT SAFETY INFORMATION

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 and full Prescribing Information, including Boxed Warning, at ARIKAYCE.com.

IMPORTANT SAFETY INFORMATION (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
- **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
- 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.**

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.

Please see previous Important Safety Information and full Prescribing Information, including Boxed Warning, at ARIKAYCE.com.

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