



Limited Population

Create space for treatment in your day

Mycobacterium avium complex (MAC) lung disease is tough, and can take time to treat and manage. Additionally, figuring out how to work a new treatment into your regular routine can be challenging. This worksheet was designed to help you and your doctor decide when, where, and how to fit your treatment into your daily schedule. A goal of treatment is to test MAC-negative—ask your doctor how you'll track this goal.

My time



Taking your treatment at the same time each day can help it become part of your routine. Treatment will take 14-20 minutes, plus the time it takes to prepare and clean your nebulizer. This time will vary depending on your familiarity with the procedures, but you should set aside at least 35-45 minutes altogether. To find the best time, it may help to first think about what your day is like now. **To get started, write out the activities you do each day.**

My mornings tend to be:

- Busy
- Calm
- Unpredictable/varies day to day

My afternoons tend to be:

- Busy
- Calm
- Unpredictable/varies day to day

My evenings tend to be:

- Busy
- Calm
- Unpredictable/varies day to day

Also, reflect on your daily activities and when you will have time and energy for your treatment. Then discuss what you think with your doctor and agree on a time to take your medication.

Now choose the activity and time of day to take your treatment.



My place



Choosing where you'll take your treatment is another part of creating your routine. You'll need a clean, flat surface for the device, a power outlet, and a comfortable seat. **What place might be best for you (eg, the bedroom or living room)?**



TIP: Looking at positive reminders during treatment can help each day. Try putting something that inspires you, like a family photograph or an inspirational quote, in your treatment space.

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 throughout and full [Prescribing Information](#), including Boxed Warning, at [ARIKAYCE.com](#).

My entertainment



Entertainment can make your treatment experience more pleasant. Once you've begun treatment, the entertainment you've chosen will need to be hands-free and distraction-free. **What entertainment will you use?**



My rewards



Reward yourself for continuing to work toward your treatment goals. **Take some time to jot down how you can reward yourself.**



My backup plan



Even when you have a treatment routine that works, sometimes things may change, and that's OK. It can help to think ahead and plan for these times. Here are some questions you might ask yourself to prepare for this:

What could interrupt your treatment schedule (eg, providing care for a family member)?



**When your schedule is interrupted, what's a good backup time to take your treatment?
Take some time to jot down how you can reward yourself.**



Nice work!

You've created your personalized treatment routine! Remember that your needs may change as you continue treatment, so it's OK to revisit your routine and make changes. Be sure to bring this with you to your next doctor's appointment to help with the discussion about your treatment routine.

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

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ARIKAYCE[®]
(amikacin liposome
inhalation suspension)
Limited Population

IMPORTANT SAFETY INFORMATION (cont'd)

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

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

