



Limited Population

A checklist for traveling with medication

There's plenty to prepare and think about when you're traveling with medication. Before going away, use this checklist to plan ahead so you can stay on ARIKAYCE as your doctor prescribed.

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

Your pre-trip to-do list

Traveling with your medication doesn't have to be stressful. Use this checklist to help you manage how to pack and administer your treatment while away from home

- Talk to your doctor about your travel plans and treatment schedule**
 - If you're traveling in a different time zone, your doctor may want to adjust your treatment schedule accordingly

- Pack enough medication and disinfectant supplies to last for the duration of your trip plus extra in case of travel delays or a change of plans**
 - If you'll be away for only 1 night, disinfect your device in advance
 - Bring clear liquid dish soap, a slotted spoon, a lint-free towel, and a spare handset and aerosol head
 - You can have distilled water delivered from a store close to your destination or order it online and have it shipped there, allowing enough time for it to arrive

- If unsure of power outlet requirements, you may want to pack a power cord or strip, extra AA batteries, and adapters for foreign countries**

- Bring your medical records with you** including a list of medical conditions, allergies, names and dosages of your medications, contact information of physicians, and a copy of your prescription(s)

- Keep medicines in their original labeled containers**
 - Make sure they are clearly labeled with your full name (as listed on your passport), doctor's name, generic and brand name, and exact dose

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.

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ARIKAYCE[®]
(amikacin liposome
inhalation suspension)
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- ✓ **Don't pack medication in luggage that will be exposed to extreme conditions, like freezing temperatures**
 - If your medication freezes it will become unusable
 - If possible, pack your medication and device materials in your carry-on bag, and alert TSA when passing through security that you have medically necessary liquids with you. TSA allows liquid medications to exceed the 3.4-ounce restriction
- ✓ **If you are staying with family or friends, let them know in advance what you will need for cleaning and disinfecting your device**
- ✓ **If you are staying at a hotel or rental, try to book a location with its own kitchen or access to one**
 - If there isn't one, ask the concierge or front desk staff in advance what options are available
 - Make sure the kitchen includes supplies like a large bowl/soaking tub and a pot for cleaning and disinfecting your device

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
- **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.

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Additional travel considerations



Preparing for takeoff

When booking a flight, consult the TSA website for the latest updates at [TSA.gov](https://www.tsa.gov) and click on “Disabilities and Medical Conditions”

- It is recommended that all medication and accessories be clearly labeled to facilitate the security screening process
- Inform the TSA officer that you have medically necessary liquids and/or medications, remove them from your carry-on bag, and separate them from other belongings before the screening begins

Have your doctor write a letter explaining that you need to travel with medication and then have it translated into the language of the country of your destination – in case airport security at your destination asks for it

Pack a travel-size clear liquid dish soap container that meets TSA guidelines

- This ensures your medication is always with you in case of misplaced checked luggage and won't be exposed to extreme temperature changes

For more information, contact TSA Cares at: [TSA.gov/travel/passenger-support](https://www.tsa.gov/travel/passenger-support)

TSA Cares provides travelers who have disabilities, medical conditions, and other special circumstances with additional assistance during the security screening process

Call 1-855-787-2227 (weekdays: 8 AM to 11 PM ET, weekends/holidays: 9 AM to 8 PM ET) 72 hours prior to traveling with questions about screening policies, procedures, and what to expect at the security checkpoint

IMPORTANT SAFETY INFORMATION (cont'd)

ARIKAYCE can cause serious side effects, including: (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

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Taking a cruise

Before you book your trip, reach out to the cruise line to inform them of your medical condition

- Ask the ship concierge or guest services in advance if distilled water is provided free of charge or if you are required to bring everything you'll need
- While boiling water in rooms is usually not allowed, some cruise lines provide a dedicated area where you can disinfect your device



Traveling internationally

Contact the US embassy in the country of your destination to learn if any rules or restrictions apply to bringing prescription medications into the country of your destination

Have a medical travel letter translated into the language of your destination

Consult the TSA website for regulations by going to [TSA.gov](https://www.tsa.gov) and clicking on "Disabilities and Medical Conditions"

Check the electrical requirements of your destination and bring the appropriate travel adapter/converter

The Centers for Disease Control and Prevention (CDC) recommends the following tips to avoid medicine-related issues and violating any local laws while traveling to another country:

- **Many countries only allow you to bring a 30-day supply** of certain medicines and require the traveler to carry a prescription or a medical certificate

You can find the latest CDC updates:

<https://wwwnc.cdc.gov/travel/page/travel-abroad-with-medicine>

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.

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The background features a light purple, stylized line-art illustration of the Statue of Liberty on the right, holding a torch aloft. To the left and in the foreground, there are simplified outlines of city buildings, some with small dots representing windows. The overall aesthetic is clean and modern.

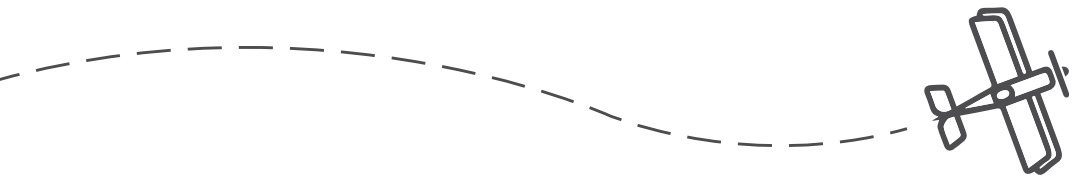
Add some color to your trip!

Did you know that coloring
can be a great way to
unwind during your trip?
Enjoy coloring in these pages
while you're traveling.

Let's Travel



New York



Washington DC



San Francisco

IMPORTANT SAFETY INFORMATION (cont'd)

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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