



## Limited Population

# Prepare for doctor visits throughout your ARIKAYCE treatment journey with the Doctor Visit Checklist

Whether you are just starting treatment with ARIKAYCE or have been on your journey for a while, this checklist is designed to help you keep the lines of communication open with your doctor.

Before your next doctor's visit, review the key questions and topics, and jot down any notes that you'd like to discuss. You can bring this checklist to your next appointment and use it as a starting point for your conversation.

Your Name: 

Doctor's Name: 

## Using the checklist

Find the section within the Doctor Visit Checklist that best describes where you are on your treatment journey.

Click below:

**I AM starting on ARIKAYCE**

**I AM more than 6 months into my ARIKAYCE journey**

**I AM in months 1–6 of my ARIKAYCE journey**

**I AM considering stopping my ARIKAYCE treatment**

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.

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 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.**

**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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# I AM starting on ARIKAYCE

Beginning a new treatment can be challenging, especially since it may require you to adjust your daily routine. Review these questions, as well as the checklist of important topics you may want to discuss. Then use the space provided to record your doctor's answers.

Appointment date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Date starting ARIKAYCE treatment: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Key questions for my doctor

- ① How long can I expect to be taking ARIKAYCE? 
- ② How will we set and track my treatment goals? 
- ③ When will I be retested for MAC lung disease? 
- ④ How often will I see you for follow-up appointments? 
- ⑤ What should I do if I experience any side effects? 
- ⑥ Are there any support resources for people taking ARIKAYCE? 

MAC=Mycobacterium avium complex.

## My checklist

### Some topics I'd like to discuss are:

- |  |  |
|--|--|
| <input type="checkbox"/> Changes in my symptoms                                      | <input type="checkbox"/> My important treatment milestones     |
| <input type="checkbox"/> Changes in how I may feel or the things I may be able to do | <input type="checkbox"/> Reducing my exposure to MAC bacteria  |
| <input type="checkbox"/> Any side effects I may experience                           | <input type="checkbox"/> Nutritional or dietary considerations |
| <input type="checkbox"/> Questions about my ARIKAYCE treatment                       | <input type="checkbox"/> Exercise recommendations              |

Notes: 

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These are sample questions to help get the conversation started between you and your doctor. They are not intended to take the place of a medical evaluation, examination, advice, consultation, diagnosis, or treatment. Always consult your doctor for all medical- and health-related matters.

## IMPORTANT SAFETY INFORMATION AND BOXED WARNING (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

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## I AM in months 1–6 of my ARIKAYCE journey

After taking ARIKAYCE for a few months, there may be some things you want to discuss with your doctor, like side effect management, or creating an ARIKAYCE routine. MAC lung disease can take time to treat.




Consider asking the following questions, and make sure to give your doctor updates using the checklist below.

Appointment date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Time since adding ARIKAYCE: \_\_\_\_ month(s) \_\_\_\_ weeks

Results of latest sputum test: ☐ MAC-positive ☐ MAC-negative

## Key questions for my doctor

- 1 How will we track my treatment goals? 
- 2 Is there anything I should be doing differently? 
- 3 What should I do if I am experiencing side effects? 

## My checklist

### Some topics I'd like to discuss are:

- |  |  |
|--|--|
| <input type="checkbox"/> Changes in my symptoms since my last visit  | <input type="checkbox"/> My important treatment milestones     |
| <input type="checkbox"/> Changes in how I have been feeling or the things I'm able to do since my last visit | <input type="checkbox"/> Reducing my exposure to MAC bacteria  |
| <input type="checkbox"/> Any side effects experienced since my last visit                                    | <input type="checkbox"/> Nutritional or dietary considerations |
| <input type="checkbox"/> Questions about my ARIKAYCE treatment since my last visit                           | <input type="checkbox"/> Exercise recommendations              |

Notes: 

## IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

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

- **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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## I AM more than 6 months into my ARIKAYCE journey

Being on a long-term treatment plan can be hard. It's important to remember why you started and to stay committed to your treatment plan as prescribed. Use the checklist below to reflect on your journey and note the questions you may have for your doctor.

Appointment date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Time since adding ARIKAYCE: \_\_\_\_ month(s) \_\_\_\_ weeks

Results of latest sputum test: ☐ MAC-positive ☐ MAC-negative

## Key questions for my doctor

1 (I have tested MAC-negative)

Why is it recommended to continue treatment after testing negative?



2 (I am still testing MAC-positive)

Should I continue to take ARIKAYCE?



3 Is there anything I should be doing differently?



4 How much longer will I be on treatment?



## My checklist

Some topics I'd like to discuss are:

- |  |  |
|--|--|
| <input type="checkbox"/> Changes in my symptoms since my last visit  | <input type="checkbox"/> My important treatment milestones     |
| <input type="checkbox"/> Changes in how I have been feeling or the things I'm able to do since my last visit | <input type="checkbox"/> Reducing my exposure to MAC bacteria  |
| <input type="checkbox"/> Any side effects experienced since my last visit                                    | <input type="checkbox"/> Nutritional or dietary considerations |
| <input type="checkbox"/> Questions about my ARIKAYCE treatment since my last visit                           | <input type="checkbox"/> Exercise recommendations              |

Notes:

## 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.

These are sample questions to help get the conversation started between you and your doctor. They are not intended to take the place of a medical evaluation, examination, advice, consultation, diagnosis, or treatment. Always consult your doctor for all medical- and health-related matters.

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## I AM considering stopping my ARIKAYCE treatment

Whether you are experiencing side effects, feeling better, or have tested MAC negative, make sure you talk to your doctor before you stop treatment, so they can help you understand the next steps.

Appointment date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Time since adding ARIKAYCE: \_\_\_\_ month(s) \_\_\_\_ weeks

Results of latest sputum test: ☐ MAC-positive ☐ MAC-negative

## Key questions for my doctor

① What should I expect after stopping ARIKAYCE? 

② Should I continue to get tested for MAC after stopping ARIKAYCE? 

③ Is there anything I should do after stopping ARIKAYCE? 

**TIP:** Take a look back at your checklist to make sure all your questions have been answered by your doctor.

## My checklist

Some topics I'd like to discuss are:

- |  |  |
|--|--|
| <input type="checkbox"/> Changes in my symptoms since my last visit  | <input type="checkbox"/> My important treatment milestones     |
| <input type="checkbox"/> Changes in how I have been feeling or the things I'm able to do since my last visit | <input type="checkbox"/> Reducing my exposure to MAC bacteria  |
| <input type="checkbox"/> Any side effects experienced since my last visit                                    | <input type="checkbox"/> Nutritional or dietary considerations |
| <input type="checkbox"/> Questions about my ARIKAYCE treatment since my last visit                           | <input type="checkbox"/> Exercise recommendations              |

Notes: 

## IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

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

These are sample questions to help get the conversation started between you and your doctor. They are not intended to take the place of a medical evaluation, examination, advice, consultation, diagnosis, or treatment. Always consult your doctor for all medical- and health-related matters.

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## 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
- **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](http://www.fda.gov/medwatch).**

## 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.

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