ARIKAYCE Prescription and *inLighten™ Patient Support* program Enrollment Form

ARIKAYCE® (amikacin liposome inhalation suspension)
Limited Population

inLighten™ Patient Support

Fax: 1-800-604-6027 or **E-mail: enrollment@inlightensupport.com**
Please complete all fields on pages 1 and 3 to prevent any delays and include scanned copies of both sides of the patient's insurance card (fields marked with an asterisk [*] are required for program enrollment).

Questions?
Phone: **833-LIGHT-00** (833-544-4800)
Alternate Phone: 1-973-437-2376

PATIENT INFORMATION

*Patient First Name: _____ *Patient Last Name: _____ *MI: _____

*DOB: _____ *Gender: ☐Male ☐Female ☐Non-binary ☐Unknown Last 4 of SSN: _____

*Physical Address: _____

*City: _____ *State: _____ *ZIP: _____

*Mailing Address: _____ ☐Same as Physical Address

*Mailing City: _____ *Mailing State: _____ *Mailing ZIP: _____

*Mobile Phone: _____ Home Phone: _____ E-mail: _____

Preferred Contact Method(s): (check all that apply) ☐Phone ☐E-mail ☐Text

Preferred Time to Contact: ☐Morning ☐Afternoon ☐Evening

Preferred Contact Language: ☐English ☐Spanish ☐Other: _____

Authorized Alternate Contact: _____

Alternate Contact Phone: _____ Relationship to Patient: _____

Prescription Insurance Information *(Please Send a Copy of Insurance Card)*

*Prescription Coverage Plan Name: _____

Beneficiary/Cardholder: _____ Relationship to Cardholder: _____

*Primary Rx Insurance ID #: _____ *Group #: _____

*BIN: _____ *PCN: _____ *Phone: _____

*Primary Rx Plan Type: ☐Private/Commercial ☐Medicare Part D ☐Medicaid ☐TRICARE ☐Other

Secondary Prescription Coverage Plan Name: _____

Beneficiary/Cardholder: _____ Relationship to Cardholder: _____

Secondary Rx Insurance ID #: _____ Secondary Group #: _____

Secondary BIN: _____ Secondary PCN: _____ Secondary Insurance Phone: _____

Secondary Rx Plan Type: ☐Private/Commercial ☐Medicare Part D ☐Medicaid ☐TRICARE ☐Other

Patient Does Not Have Insurance

2 Patient Authorization Signatures

Protected Health Information Disclosure Authorization and Consent—I have read and understand the Protected Health Information Disclosure Authorization and Consent on page 2. By signing below, I authorize the disclosure of my PHI to the *inLighten Patient Support* program as described in the Protected Health Information Disclosure Authorization and Consent on page 2.

***Patient Signature 1:** _____ ***Date:** _____

Patient Support Program Enrollment Consent—I have read and understand the Patient Support Program Enrollment Consent on page 2. By signing below, I agree to enroll in the *inLighten Patient Support* program and consent to processing of my Health Information as described in the Patient Support Program Enrollment Consent on page 2.

***Patient Signature 2:** _____ ***Date:** _____

Please see Indication and Important Safety Information for ARIKAYCE, including Boxed Warning, on page 4.
Please see accompanying full Prescribing Information.

Patient Authorization may also be submitted online at enroll.inlightensupport.com

PATIENT AUTHORIZATION

Protected Health Information Disclosure Authorization and Consent

I authorize my healthcare providers, including the pharmacies I use, and my health insurance plan(s) to disclose my information, including information about me (e.g., my name, address), my health, my finances, insurance, prescriptions, pharmacy fills/claims, and medical condition ("PHI") to Insmed (the manufacturer of my prescription) and its affiliates, agents, and contractors, including the administrators of the *inLighten Patient Support* program, the dispensing pharmacies of Insmed products, and any other person or entity assisting Insmed in the administration of the *inLighten Patient Support* program (collectively, the "*inLighten Patient Support* program"), for the following purposes, collectively "Patient Support Program Purposes":

- To facilitate my participation in the *inLighten Patient Support* program;
- To investigate, verify, and determine my insurance coverage;
- To provide financial assistance and support to facilitate access to my medications as prescribed by my treating physician;
- To facilitate a voluntary training session educating on device use and successful treatment initiation;
- To determine my initial and continuing eligibility for other assistance programs;
- To contact me by phone, mail, e-mail (if my e-mail address was provided), cell phone, or text message (if my cell phone was provided) to request further information, discuss the application process, administer the *inLighten Patient Support* program, evaluate treatment progress and/or the effectiveness of the *inLighten Patient Support* program;
- For Insmed's internal business purposes of continuous improvement, including ongoing quality control;
- To send me educational materials related to my participation in the *inLighten Patient Support* program; and
- To help ensure the accuracy and completeness of my applications.

I understand that my pharmacy provider may receive financial remuneration from Insmed in exchange for my PHI and/or for any therapy support services provided to me. I also understand that once my PHI has been disclosed under this authorization, federal privacy laws may no longer protect it and it may be subject to further disclosure. I further understand that if I decline to sign this authorization, that will not affect my eligibility for health plan benefits and treatment by my healthcare providers, but I will not be able to participate in the *inLighten Patient Support* program. I understand I have the right to revoke my authorization for any and all purposes at any time, and that I may do so by calling 833-544-4800 (alternate phone 1-973-437-2376) or writing to Insmed Incorporated, Attn: *inLighten Patient Support* program, 700 US Highway 202/206, Bridgewater, NJ 08807. If I revoke this authorization, the *inLighten Patient Support* program will stop accessing, using, and disclosing my PHI thereafter, but the uses and disclosures previously made in reliance on the authorization will not be deemed invalid. This authorization expires ten (10) years from the date of my signature, unless specified or mandated to be shorter by applicable state law. I understand that I am entitled to a copy of this authorization once signed.

Patient Support Program Enrollment Consent

I agree to enroll in the *inLighten Patient Support* program provided by Insmed and verify that the information in the "Patient Information" section of this form is accurate and complete. I also agree that Insmed and its data processors may collect, use, and disclose my health information, including sensitive data and consumer health data, as listed below, (collectively, "Health Information") for participation in the *inLighten Patient Support* program:

- Individual health conditions, treatment, diseases, or diagnosis;
- Social, psychological, behavioral, and medical interventions;
- Health-related surgeries or procedures;
- Use or purchase of prescribed medication;
- Bodily functions, vital signs, symptoms, or measurements related to health;
- Diagnoses or diagnostic testing, treatment, or medication;
- Data that identifies me as a consumer seeking health care services; and
- Health-related data that have been derived or inferred from the above.

Insmed may collect, use, and disclose this Health Information for Patient Support Program Purposes, as defined in the Protected Health Information Disclosure Authorization and Consent.

I understand that if I consent on page 1, Insmed may disclose my Health Information to its data processors, affiliates, and to the following third parties: Pharmacies, Co-Pay Administrators, Fulfillment/Logistics Partners, and Patient Educators. Detailed information about these third parties can be found at ARIKAYCE.com/support.

You are not required to consent to processing of your Health Information for these purposes. However, if you do not consent, you will not be able to participate in the *inLighten Patient Support* program, as collection of your Health Information is necessary for Insmed to facilitate your participation. If you consent on page 1, you have the right to withdraw your consent at any time. You can do so by calling 833-544-4800 (alternate phone 1-973-437-2376) or writing to Insmed Incorporated, Attn: *inLighten Patient Support* program, 700 US Highway 202/206, Bridgewater, NJ 08807.

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Please see accompanying full Prescribing Information.

insmed®

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Alternate Phone: 1-973-437-2376

HEALTHCARE PROFESSIONAL & PRESCRIPTION INFORMATION

*Prescriber First Name: _____ *Prescriber Last Name: _____

*Practice Name: _____ Specialty: _____

*Address: _____ *City: _____ *State: _____ *ZIP: _____

*Phone: _____ *Fax: _____ *NPI #: _____

Office Contact Name: _____ Office Contact Phone: _____

Office Contact E-mail: _____

If Applicable, Check Appropriate Box for Specialty Pharmacy Preference:
☐ No Preference ☐ Maxor Specialty Pharmacy ☐ PANTHERx RARE Pharmacy ☐ Amber Specialty Pharmacy

Please note if ARIKAYCE is being ordered through: ☐ VA ☐ 340B entity

Official Prescription Information

*Patient First Name: _____ *Patient Last Name: _____ *DOB: _____

☐ ***Product:** ARIKAYCE® (amikacin liposome inhalation suspension)

Dosing Info: Once-Daily 590 mg/8.4 mL

Quantity: 28-Day Supply: 28-Vial Pack
(28 Vials of Medication, 4 Aerosol Heads, and 1 Handset)
(First Shipment Includes Lamira® System)

☐ ***Number of Refills:** _____

New York prescribers, please submit prescription on an original NY State prescription blank. The prescriber is to comply with his or her state-specific form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

***Substitution Permitted?** ☐ Yes ☐ No

Prescriber Certification

I certify that the above therapy is medically necessary, and that the information provided is accurate to the best of my knowledge. By submitting this form, I certify that I am the prescriber who has prescribed ARIKAYCE to the previously identified patient, that the patient authorized the disclosure of their personal health information to Insmed, that I provided the patient with a description of the *inLighten Patient Support* program, and that the patient has given permission to be contacted by Insmed regarding the *inLighten Patient Support* program. I authorize the *inLighten Patient Support* program to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy.

***Prescriber Signature:** _____ ***Date:** _____
No stamped signatures accepted

Special Instructions:

☐ Pre-treatment with inhaled bronchodilator due to history of hyperreactive airway disease

Please see Indication and Important Safety Information for ARIKAYCE, including Boxed Warning, on page 4.
Please see accompanying full Prescribing Information.

INDICATION

LIMITED POPULATION: ARIKAYCE® is indicated in adults, who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for ARIKAYCE are currently available, reserve ARIKAYCE for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitation of Use: ARIKAYCE has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of ARIKAYCE is not recommended for patients with non-refractory MAC lung disease.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING

WARNING: RISK OF INCREASED RESPIRATORY ADVERSE REACTIONS

ARIKAYCE has been associated with an increased risk of respiratory adverse reactions, including hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases.

Hypersensitivity Pneumonitis has been reported with the use of ARIKAYCE in the clinical trials. Hypersensitivity pneumonitis (reported as allergic alveolitis, pneumonitis, interstitial lung disease, allergic reaction to ARIKAYCE) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (3.1%) compared to patients treated with background regimen alone (0%). Most patients with hypersensitivity pneumonitis discontinued treatment with ARIKAYCE and received treatment with corticosteroids. If hypersensitivity pneumonitis occurs, discontinue ARIKAYCE and manage patients as medically appropriate.

Hemoptysis has been reported with the use of ARIKAYCE in the clinical trials. Hemoptysis was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (18.4%) compared to patients treated with background regimen alone (13.4%). If hemoptysis occurs, manage patients as medically appropriate.

Bronchospasm has been reported with the use of ARIKAYCE in the clinical trials. Bronchospasm (reported as asthma, bronchial hyperreactivity, bronchospasm, dyspnea, dyspnea exertional, prolonged expiration, throat tightness, wheezing) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (28.7%) compared to patients treated with background regimen alone (10.7%). If bronchospasm occurs during the use of ARIKAYCE, treat patients as medically appropriate.

Exacerbations of underlying pulmonary disease have been reported with the use of ARIKAYCE in the clinical trials. Exacerbations of underlying pulmonary disease (reported as chronic obstructive pulmonary disease (COPD), infective exacerbation of COPD, infective exacerbation of bronchiectasis) have been reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (15.2%) compared to patients treated with background regimen alone (9.8%). If exacerbations of underlying pulmonary disease occur during the use of ARIKAYCE, treat patients as medically appropriate.

Anaphylaxis and Hypersensitivity Reactions: Serious and potentially life-threatening hypersensitivity reactions, including anaphylaxis, have been reported in patients taking ARIKAYCE. Signs and symptoms include acute onset of skin and mucosal tissue hypersensitivity reactions (hives, itching, flushing, swollen lips/tongue/uvula), respiratory difficulty (shortness of breath, wheezing, stridor, cough), gastrointestinal symptoms (nausea, vomiting, diarrhea, crampy abdominal pain), and cardiovascular signs and symptoms of anaphylaxis (tachycardia, low blood pressure, syncope, incontinence, dizziness). Before therapy with ARIKAYCE is instituted, evaluate for previous hypersensitivity reactions to aminoglycosides. If anaphylaxis or a hypersensitivity reaction occurs, discontinue ARIKAYCE and institute appropriate supportive measures.

Ototoxicity has been reported with the use of ARIKAYCE in the clinical trials. Ototoxicity (including deafness, dizziness, presyncope, tinnitus, and vertigo) were reported with a higher frequency in patients treated with ARIKAYCE plus background regimen (17%) compared to patients treated with background regimen alone (9.8%). This was primarily driven by tinnitus (8.1% in ARIKAYCE plus background regimen vs 0.9% in the background regimen alone arm) and dizziness (6.3% in ARIKAYCE plus background regimen vs 2.7% in the background regimen alone arm). Closely monitor patients with known or suspected auditory or vestibular dysfunction during treatment with ARIKAYCE. If ototoxicity occurs, manage patients as medically appropriate, including potentially discontinuing ARIKAYCE.

Nephrotoxicity was observed during the clinical trials of ARIKAYCE in patients with MAC lung disease but not at a higher frequency than background regimen alone. Nephrotoxicity has been associated with the aminoglycosides. Close monitoring of patients with known or suspected renal dysfunction may be needed when prescribing ARIKAYCE.

Neuromuscular Blockade: Patients with neuromuscular disorders were not enrolled in ARIKAYCE clinical trials. Aminoglycosides may aggravate muscle weakness by blocking the release of acetylcholine at neuromuscular junctions. Closely monitor patients with known or suspected neuromuscular disorders, such as myasthenia gravis. If neuromuscular blockade occurs, it may be reversed by the administration of calcium salts but mechanical respiratory assistance may be necessary.

Embryo-Fetal Toxicity: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides, including ARIKAYCE, may be associated with total, irreversible, bilateral congenital deafness in pediatric patients exposed *in utero*. Patients who use ARIKAYCE during pregnancy, or become pregnant while taking ARIKAYCE should be apprised of the potential hazard to the fetus.

Contraindications: ARIKAYCE is contraindicated in patients with known hypersensitivity to any aminoglycoside.

Most Common Adverse Reactions: The most common adverse reactions in Trial 1 at an incidence ≥5% for patients using ARIKAYCE plus background regimen compared to patients treated with background regimen alone were dysphonia (48% vs 2%), cough (40% vs 17%), bronchospasm (29% vs 11%), hemoptysis (18% vs 13%), musculoskeletal pain (18% vs 9%), upper airway irritation (18% vs 2%), ototoxicity (17% vs 10%), fatigue and asthenia (16% vs 10%), exacerbation of underlying pulmonary disease (15% vs 10%), diarrhea (13% vs 5%), nausea (12% vs 4%), headache (10% vs 5%), pneumonia (9% vs 9%), pyrexia (8% vs 5%), decreased weight (7% vs 1%), vomiting (7% vs 4%), rash (6% vs 1%), change in sputum (6% vs 1%), and chest discomfort (5% vs 3%).

Drug Interactions: Avoid concomitant use of ARIKAYCE with medications associated with neurotoxicity, nephrotoxicity, and ototoxicity. Some diuretics can enhance aminoglycoside toxicity by altering aminoglycoside concentrations in serum and tissue. Avoid concomitant use of ARIKAYCE with ethacrynic acid, furosemide, urea, or intravenous mannitol.

Overdosage: Adverse reactions specifically associated with overdose of ARIKAYCE have not been identified. Acute toxicity should be treated with immediate withdrawal of ARIKAYCE, and baseline tests of renal function should be undertaken. Hemodialysis may be helpful in removing amikacin from the body. In all cases of suspected overdosage, physicians should contact the Regional Poison Control Center for information about effective treatment.

Please see accompanying full Prescribing Information.

Insmed®

What to expect when starting ARIKAYCE

Understanding the *inLighten*™ *Patient Support* program

Living with this condition is not easy, and neither is starting a new treatment. *inLighten* is here to provide you with important information and ongoing support throughout your ARIKAYCE® (amikacin liposome inhalation suspension) journey.

Step 1: Being prescribed ARIKAYCE

- You can choose to enroll in *inLighten*

Step 2: Welcome to the program

- Your *inLighten Coordinator* contacts you to welcome you to the program
- You receive a Welcome Pack in the mail
- Your voluntary *inLighten Educator**, a nurse or respiratory therapist, discusses the Welcome Pack with you

*It is not the role of the *inLighten Educator* to provide medical or treatment advice or replace the instructions you receive from your healthcare provider.

Step 3: Receiving ARIKAYCE

- ARIKAYCE arrives at your home, along with a device to help you take it, and a Getting Started box

Step 4: Voluntary device training

- You may choose to receive in-home or virtual training from your *inLighten Educator* to help you take your medication

Step 5: Ongoing support

- Your *inLighten Coordinator* will be in touch throughout your treatment journey to provide focused education and support along the way

If you have questions about *inLighten*, please call 833-LIGHT-00 (833-544-4800)
Monday – Friday, 8 AM – 8 PM Eastern Time.
For more information about ARIKAYCE go to ARIKAYCE.com

inLighten Coordinator Name: _____

inLighten Coordinator Tel: _____

inLighten Educator Name: _____

Please see Important Safety Information for ARIKAYCE, including Boxed Warning. Please see accompanying full Prescribing Information.

ARIKAYCE®
(amikacin liposome inhalation suspension)
Limited Population

inLighten™ Patient Support

inLighten Welcome Pack

Included in the *inLighten* Welcome Pack:

- Welcome letter
- How *inLighten* works
- Getting started with ARIKAYCE
- Preparing for doctor visits
- Living with MAC lung disease
- Reducing exposure to MAC
- Airway clearing techniques
- Taking ARIKAYCE
- Traveling tips
- Insurance approval process
- *inLighten Coordinator* business card
- *inLighten Coordinator* magnet

MAC=*Mycobacterium avium* complex

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

Please see additional Important Safety Information for ARIKAYCE on the back cover, including Boxed Warning. Please see accompanying full Prescribing Information.

ARIKAYCE will be delivered to your door

Box 1: The ARIKAYCE 28-day Kit

You will receive a new shipment of ARIKAYCE every 4 weeks.

- **A** 1 ARIKAYCE Quick Start Guide
- **B** 1 Instructions for Use Insert
- **C** 1 Full Prescribing Information Insert
- **D** 4 Weekly Boxes
- **E** 1 Lamira® Nebulizer Handset
- **F** 28 once-daily vials of ARIKAYCE
  (1 vial to be used each day for 28 days)
  For tips and a demonstration on how to open the vial, see the **device video** on ARIKAYCE.com
- **G** 4 Lamira Aerosol Heads
  (1 in each weekly box)
- **H** 1 Cooler Return Form
  The Cooler Pack and Ice Packs may be returned to your specialty pharmacy (your shipment will include further instructions). Contact your *inLighten Coordinator* if you have any questions about how the program works

Box 2: The Lamira® Nebulizer System for ARIKAYCE

Treatment will take 14-20 minutes, plus time for prep and cleaning.

- **A** 1 Carrying Case
- **B** 1 A/C Power Supply
- **C** 4 AA Batteries
- **D** 1 Connection Cord
- **E** 1 Instructions for Use Insert
- **F** 1 Full Prescribing Information Insert
- **G** 1 Spare Lamira Aerosol Head
- **H** 1 eBase® Controller
- **I** 1 Spare Lamira Nebulizer Handset

Getting started kit

The *inLighten Patient Support* program will also send you a few items as you begin treatment.

- **J** Lint-free Towel
- **K** 2-oz Dish Soap Sample
- **L** Lint-free Drying Mat
- **M** Timer

ARIKAYCE® (amikacin liposome inhalation suspension)
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inLighten™ Patient Support

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (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.**

Please see additional Important Safety Information and full Prescribing Information inside, including Boxed Warning.

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