

Thank you for downloading this prescription assistance document from NeedyMeds. We hope this program will help you get the medicine you need.

REMEMBER — Send your completed application to the address on the form, NOT to NeedyMeds.

Did you know that NeedyMeds has thousands of other free resources?

Here's a look at more ways we can help you save money on medicine and healthcare costs. Each one can be found under the "**Healthcare Savings**" tab on our website:

- **Diagnosis-Based Assistance** — NeedyMeds lists thousands of assistance programs for almost any health condition. If you are going through chemo treatment for cancer, there are programs that can help with wig costs and scalp-cooling products. We also list resources for free diabetes testing supplies, caregiver lodging support, and much more.
- **Free, Low-Cost, and Sliding Scale Clinics** — This popular collection contains information on 18,000+ free, low-cost, and sliding scale medical, dental, mental health and substance abuse clinics across the U.S. It's a great resource if you need affordable medical treatment and don't know where to go.
- **Coupons, Rebates & More** — You can use the NeedyMeds website to find 2,600+ cost-saving opportunities for both prescription and over-the-counter drugs and medical supplies.
- **Medical Transportation** — Need help getting to the doctor's office or medical facility? You may be eligible for financial assistance if you meet certain requirements.

NeedyMeds also offers information on diagnosis-based camps and retreats, recreational programs, scholarships, government programs, \$4 generic drug programs, and more.

Finally, I want to tell you about the NeedyMeds Drug Discount Card. Thousands of people use this free, anonymous, and easy-to-use tool to get the best price on their medications. Use the card to get discounts on lab tests and also to save 40% on durable medical equipment. To date, our drug discount card has saved patients over \$300,000,000. Check out the following page to learn more.


Feel free to call our toll-free helpline if you have any questions. We can be reached at 1-800-503-6897 Monday-Friday, 9am-5pm Eastern Time.

Thank you for using NeedyMeds. Please let us know if we can do anything else to help you afford the costs of your healthcare.



Rich Sagall, MD
President, NeedyMeds

Clip the card and save



DRUG DISCOUNT CARD

BIN: 020750
RX PCN: NMeds
RX GRP: PDFPDF
ID: NMNA019309901930

Customer Care
1-888-602-2978

This is a drug discount program, not an insurance plan.

NeedyMeds Drug Discount Card
www.needymeds.org

Patient: You may use this card at any of over 65,000 participating pharmacies to save on all prescription medicines. You cannot use this card with Medicare including part D, Medicaid, or any other state or federal programs unless you choose not to use your government-sponsored program. In addition, you cannot use this card with any health insurance program, but you can use it in place of your insurance if the card offers a better price. For questions call 1-888-602-2978 or visit www.drugdiscountcardinfo.com.

Pharmacist: Administered by Medical Security Company, LLC, Tucson, AZ.

Pharmacy Help Desk: 1-800-404-1031.



- Save up to 80% on medications*
- Use at over 65,000 pharmacies nationwide including all major chains
- Share the card with friends and family

- Use the card as often as needed
- Free, no fees or registration
- Never expires

What will receive a discount?

All prescription medications are eligible for savings, including over-the-counter medicines and medical supplies written as a prescription, as well as human-equivalent pet medications with a prescription by a veterinarian.

Save up to 40% off durable medical equipment, including canes, crutches, splints, incontinence supplies and more. You can also save on diabetic supplies such as glucose meters, test strips, lancets and diabetic shoes. Visit www.needymeds.org/dme to learn more.

You can also save an extra 5% on affordable lab tests and online results. No doctor's order or insurance needed. Visit www.needymeds.org/L2L for more information.

What if I have insurance?

Anyone can use the card, but it can't be combined with state or federal insurance. You can use the card instead of insurance if:

- A drug isn't covered by your insurance
- Your insurance has no drug coverage
- You have a high drug deductible
- You have met a low medicine cap
- The card offers a better price than your copay
- You are in the Medicare Part D donut hole

To obtain a plastic drug discount card, send a self-addressed, stamped envelope to:

NeedyMeds Drug Discount Card
50 Whittemore St.
Gloucester, MA 01930

The card is not valid in combination with insurance plans, including Medicare, Medicaid or any state or federal prescription insurance. The card can be used only if you decide not to use your government-sponsored drug plan for your purchases.

* Average savings of 60%, with potential savings of up to 80% or more (based on 2018 national program savings data). All prescription medications are eligible for savings.

This is a drug discount program, not an insurance plan. Discounts are available exclusively through participating pharmacies. The range of the discounts will vary depending on the type of prescription and the pharmacy chosen. This program does not make payments directly to pharmacies. Users are required to pay for all prescription purchases. Cannot be used in conjunction with insurance. You may call 1-888-602-2978 with questions or concerns or to obtain further information.

ARIKAYCE[®] Prescription and Arikares[®] Support Program Enrollment Form



Fax: 1-800-604-6027 or E-mail: enrollment@arikares.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 mandatory/required).



Questions?

Phone: 1-833-ARIKARE (1-833-274-5273)
Alternate Phone: 1-973-437-2376

PATIENT INFORMATION

*Patient First Name: _____ *Patient Last Name: _____ *MI: _____
*DOB: _____ *Gender: Male Female Last 4 of SSN: _____
*Physical Address: _____
*City: _____ *State: _____ *ZIP: _____
*Mailing Address: _____ Same as Physical Address
*City: _____ *State: _____ *ZIP: _____
*Primary Phone: _____ Secondary 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 Rx Plan Name: _____
Beneficiary/Cardholder: _____ Relationship to Cardholder: _____
Secondary Rx Insurance ID #: _____ Group #: _____
BIN: _____ PCN: _____ Phone: _____
Secondary Rx Plan Type: Private/Commercial Medicare Part D Medicaid TRICARE Other

Patient Does Not Have Insurance

Patient Authorization Signature

Information Disclosure—I have read and understand the Patient Authorization on page 2, and I agree to allow My Information (as defined in the Patient Authorization) to be used and shared as described in the Authorization.

*Patient Signature: _____ *Date: _____

Program Enrollment—By signing below, I agree to enroll in the Arikares Support Program and verify that the information in the "Patient Information" section of this form is accurate and complete.

*Patient Signature: _____ *Date: _____

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

PATIENT AUTHORIZATION

By signing the Patient Authorization block on page 1, I authorize my healthcare providers, including the pharmacies I use, and my health insurance plan(s) to disclose my personal information, including information about me (eg, my name, address) and my health, including my finances, insurance, prescriptions, pharmacy fills/claims, and medical condition (“My Information”) to Insmmed (the manufacturer of ARIKAYCE® [amikacin liposome inhalation suspension]) and its affiliates, agents, and contractors, including the administrators of the Insmmed *Arikares*® *Support Program*, the dispensing pharmacies of Insmmed products, and any other person or entity assisting Insmmed in the administration of the *Arikares* Program (collectively, the “Insmmed *Arikares* Team”), for the purposes listed below:

1. To investigate, verify, and determine my insurance coverage for ARIKAYCE
2. To provide financial assistance, and support to facilitate access to ARIKAYCE and the Lamira® System as prescribed by my treating physician
3. To facilitate a voluntary training session educating on device use and successful treatment initiation
4. To determine my initial and continuing eligibility for other assistance programs
5. 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 Program, evaluate treatment progress and/or the effectiveness of the Program, and to conduct market research
6. For Insmmed’s internal business purposes of continuous improvement, including ongoing quality control
7. To help ensure the accuracy and completeness of my applications
8. To send me marketing information, offers, and educational materials related to MAC (*Mycobacterium avium* complex) lung disease and/or ARIKAYCE

I understand that my pharmacy provider may receive remuneration from Insmmed in exchange for the health information provided and/or for any therapy support services provided to me. I also understand that once My Information has been disclosed under this Authorization, federal privacy laws may no longer protect it and that it may be subject to further disclosure. I specifically authorize the Insmmed *Arikares* Team to use and disclose My Information for the purposes listed above. 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 have access to the education and services available through the *Arikares Support Program*. I understand that I may revoke this Authorization at any time by calling **1-833-274-5273** (alternate phone 1-973-437-2376) or writing to Insmmed Incorporated, Attn: Arikares, 700 US Highway 202/206, Bridgewater, NJ 08807. If I do revoke this Authorization, the Insmmed *Arikares* Team will stop accessing, using, and disclosing My Information 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 Program Enrollment signature on page 1, 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.

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



ARIKAYCE[®] Prescription and Arikares[®] Support Program Enrollment Form



Fax: 1-800-604-6027 or E-mail: enrollment@arikares.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 mandatory/required).



Questions?

Phone: 1-833-ARIKARE (1-833-274-5273)
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 Specialty Pharmacy



Official Prescription Information

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

*Product: ARIKAYCE[®] (amikacin liposome inhalation suspension) *Quantity: 28-Day Supply: 28-Vial Pack (28 Vials of Medication, 4 Aerosol Heads, and 1 Handset)
(First Shipment Includes Lamira[®] System)

*Dosing Info: Once-Daily 590 mg/8.4 mL

*# 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. I certify that I am the prescriber who has prescribed ARIKAYCE to the previously identified patient and that I provided the patient with a description of the Arikares Support Program. I authorize the Arikares 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:

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

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 $\geq 5\%$ 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.

