Arikayce (amikacin)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Arikayce
- **Generic name:** Amikacin
- **Pharmacological class:** Aminoglycoside
- **Strength and Formulation:** 590mg/8.4mL; per vial; liposome suspension for oral inhalation
- **Manufacturer:** Insmed Incorporated
- **How supplied:** Vials (10mL)—28 (w. Lamira Nebulizer + supplies)
- **Legal Classification:** Rx

Arikayce


LIFT
NDC 71558-590-07
Week 1
ARIKAYCE
(amikacin liposome inhalation suspension)
590 mg/8.4 mL vials
Limited Population*
1-833-ARIKARE
(1-833-274-5273)
Attention Patients:
Week 1
ARIKAYCE

Indication

- Treatment of *Mycobacterium avium* complex (MAC) lung disease, as part of a combination antibacterial regimen, in adults with limited or no alternative treatment options who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen

Limitations of Use

- Only studied in patients with refractory MAC lung disease
- Not recommended for patients with non-refractory MAC lung disease

Dosage & Administration

- Use with **Lamira Nebulizer system** only
- Consider pre-treatment with short-acting selective beta-2 agonist in known hyperreactive airway disease, COPD, asthma or bronchospasm
- **≥18yrs**: Inhale orally contents of 1 vial (590mg) once daily

Considerations for Special Populations

- **Pregnancy:** Aminoglycosides can cause fetal harm when administered to pregnant women
- **Nursing mothers:** Consider benefits of breastfeeding and any potential adverse effects on child
- **Pediatric:** <18yrs: not established
- **Elderly:** Monitor renal function
- **Renal impairment:** Renal function should be monitored in patients with known or suspected impairment

Boxed Warning

- Risk of increased **respiratory adverse reactions**
  - These include hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases

Warnings/Precautions

- Increased risk of **respiratory adverse reactions** potentially leading to hospitalizations
- Discontinue if hypersensitivity pneumonitis occurs; manage appropriately
- Known or suspected **auditory/vestibular dysfunction**; monitor closely; if ototoxicity occurs, manage and discontinue if appropriate
- Known or suspected **renal dysfunction** or **neuromuscular disorders** (eg, myasthenia gravis); monitor closely

Interactions

- Avoid concomitant neurotoxic, nephrotoxic, and ototoxic drugs
- Avoid concomitant furosemide, ethacrynic acid, urea, IV mannitol
- Diuretics may increase toxicity

Adverse Reactions

- **Most common** (incidence ≥10% and higher than control): dysphonia, cough, bronchospasm, hemoptysis, ototoxicity, upper airway irritation, musculoskeletal pain, fatigue/asthenia, exacerbation of underlying pulmonary disease, diarrhea, nausea,
- **Others**: pneumonia, headache, pyrexia, vomiting, rash, weight decreased, change in sputum, chest discomfort, hypersensitivity pneumonitis, nephrotoxicity, neuromuscular blockade

Mechanism of Action

- Amikacin is a polycationic, semisynthetic, bactericidal aminoglycoside
- It enters the bacterial cell by binding to negatively charged components of the bacterial cell wall disrupting the overall architecture of the cell wall
- The primary mechanism of action is the disruption and inhibition of protein synthesis in the target bacteria by binding to the 30S ribosomal subunit

Clinical Studies

- The efficacy of Arikayce was evaluated in Trial 1, an open-label, randomized, multicenter study involving 336 patients with refractory (MAC) lung disease

- **Refractory MAC** was defined as failing to achieve negative sputum cultures after a minimum duration of 6 consecutive months of background regimen therapy that was either ongoing or discontinued no more than 12 months before the screening visit

Clinical Studies

- Patients either received Arikayce plus a background regimen (N=224) or background regimen alone (N=112)
- At the time of enrollment, 89.9% of patients were either on a guideline-based or off guideline-based therapy for MAC for less than 3 months while 10.1% were off treatment for 3-12 months before enrollment
- Overall, 54.9% of patients were receiving a triple background regimen of a macrolide, a rifamycin, and ethambutol at baseline

Clinical Studies

- The **surrogate efficacy endpoint** was based on achieving culture conversion, defined as 3 consecutive monthly negative sputum cultures, by Month 6

- The **date of conversion** was the date of the first of the 3 negative monthly cultures, which had to be achieved by Month 4 in order to meet the endpoint by Month 6

Clinical Studies

- Study results showed that the proportion of patients achieving culture conversion by Month 6 was significantly greater in patients treated with Arikayce plus background regimen (29%) compared with patients treated with background regimen alone (8.9%) [*P* <.0001]

Clinical Studies

- Additionally, **sustained sputum culture conversion** through Month 6 was analyzed, which was defined as consecutive negative sputum cultures with no positive culture on solid media or no more than 2 consecutive positive cultures in liquid media following achieving initial culture conversion

- The analysis showed that 27.7% of patients in the Arikayce + background regimen arm vs 6.3% in the background regimen alone arm had sustained sputum culture conversion through Month 6

Clinical Studies

- Additional endpoints to assess the clinical benefit of Arikayce (eg, change from baseline in 6-minute walk test distance, Saint George's Respiratory Questionnaire) did not demonstrate clinical benefit by Month 6
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

https://www.empr.com/drug/arikayce/