ARIKAYCE LIPOSOMAL 590 MG NEBULISER DISPERSION (AMIKACIN SULFATE) - ABBREVIATED PRESCRIBING INFORMATION (API)
Prescribers are recommended to consult the summary of product characteristics before prescribing.

Presentations
Each vial contains amikacin sulfate equivalent to 590 mg amikacin in a liposomal formulation. The mean delivered dose per vial is approximately 312 mg of amikacin.

Indication
Arikayce is indicated for the treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Posology and method of administration
ARIKAYCE liposomal treatment should be initiated and managed by physicians experienced in the treatment of non-tuberculous lung disease due to Mycobacterium avium Complex. ARIKAYCE liposomal should be used in conjunction with other antibacterial agents active against Mycobacterium avium Complex lung infections.

Arikayce recommended dosage: one vial (590 mg) administered once daily, by oral inhalation.

Duration of treatment: Treatment with Arikayce, as part of a combination antibacterial regimen, should be continued for 12 months after sputum culture conversion. Treatment should not continue beyond a maximum of 6 months if sputum culture conversion (SCC) has not been confirmed by then. The maximum duration of treatment should not exceed 18 months.

Hepatic/renal impairment: Arikayce has not been studied in patients with hepatic or renal impairment. No dose adjustments based on hepatic impairment are required since amikacin is not hepatically metabolised. Use is contraindicated in severe renal impairment.

Paediatrics: The safety and efficacy of Arikayce in paediatric patients below 18 years of age have not been established. No data are available.

Missed doses: If a daily dose of Arikayce is missed, the next dose should be administered the next day. A double dose should not be given to make up for the missed dose.

Method of administration: Arikayce is for inhalation use only. Arikayce must only be used with the Lamira Nebuliser System (nebuliser handset, aerosol head and controller). It must not be administered by any other route or using any other type of inhalation delivery system.

Refer to full SmPC for full information on posology and administration.

Contraindications
- Hypersensitivity to active substance, to any aminoglycoside antibacterial agent, or any excipient.
- Hypersensitivity to soya.
- Co-administration with any aminoglycoside administered via any route of administration.
- Severe renal impairment.

Special warnings and precautions for use
Anaphylaxis and hypersensitivity reactions: Serious and potentially life-threatening hypersensitivity reactions, including anaphylaxis, have been reported in patients taking inhaled liposomal amikacin.

Allergic alveolitis: Allergic alveolitis and pneumonitis have been reported with the use of inhaled liposomal amikacin.

Bronchospasm: Bronchospasm has been reported with the use of inhaled liposomal amikacin.

Exacerbation of underlying pulmonary disease: In clinical trials, exacerbation of underlying pulmonary disease (chronic obstructive pulmonary disease, infective exacerbation of chronic obstructive pulmonary disease, infective exacerbation of bronchiectasis) was reported with a higher frequency in patients treated with inhaled liposomal amikacin.

Ototoxicity: In clinical trials, ototoxicity, (including deafness, dizziness, presyncope, tinnitus, and vertigo) was reported with a higher frequency in patients treated with inhaled liposomal amikacin. There is an increased risk of ototoxicity in patients with mitochondrial DNA mutations (particularly the nucleotide 1555 A to G substitution in the 12S rRNA gene), even if aminoglycoside serum levels are within the recommended range during treatment. Alternative treatment options should be considered in such patients. In patients with a maternal history of relevant mutations or aminoglycoside induced deafness, alternative treatments or genetic testing prior to administration should be considered.

Nephrotoxicity: Nephrotoxicity was reported in clinical trials in patients treated with inhaled liposomal amikacin. Renal function should be monitored periodically during treatment in all patients and frequent monitoring is advised in patients with pre-existing renal dysfunction.

Neuromuscular blockade: In clinical trials, neuromuscular disorders (reported as muscle weakness, neuropathy peripheral and balance disorder) have been reported with inhaled liposomal amikacin. Use of inhaled liposomal amikacin in patients with myasthenia gravis is not recommended.

Refer to full SmPC for further information on warnings and precautions.

Interaction with other medicinal products and other forms of interaction
No clinical drug interaction studies have been conducted with inhaled liposomal amikacin.

Co-administration of inhaled liposomal amikacin with any aminoglycoside administered by any route is contraindicated.

Co-administration with any other medicinal product affecting auditory function, vestibular function or renal function (including diuretics) is not recommended.

Concurrent and/or sequential use of inhaled liposomal amikacin is not recommended with other medicinal products with neurotoxic, nephrotoxic or ototoxic potential that can enhance aminoglycoside toxicity (e.g. diuretic compounds such as ethacrynic acid, furosemide or intravenous mannitol).

Refer to full SmPC for further information on interactions.

Fertility, pregnancy and lactation
Human data on use during pregnancy or lactation are not available. No fertility studies were conducted with inhaled liposomal amikacin. As a precautionary measure, it is preferable to avoid the use of inhaled liposomal amikacin during pregnancy.

Effects on ability to drive and use machines
Amikacin has minor influence on the ability to drive and use machines. The administration of inhaled liposomal amikacin can cause dizziness and other vestibular disturbances. Patients should be advised not to drive or operate machinery while using inhaled liposomal amikacin.

Undesirable effects
The most commonly reported respiratory adverse reactions were dysphonia, cough, dyspnoea, haemoptysis, oropharyngeal pain, and bronchospasm.

Other commonly reported non-respiratory adverse reactions included fatigue, diarrhoea, infective exacerbation of bronchiectasis, and nausea.

Most common serious adverse reactions included Chronic Obstructive Pulmonary Disease (COPD), haemoptysis, and infective exacerbation of bronchiectasis.

Refer to full SmPC for further information on undesirable effects.

Overdose
Adverse reactions specifically associated with overdose of inhaled liposomal amikacin have not been identified in clinical trials. Overdose in subjects with pre-existing impaired renal function, deafness or vestibular disturbance, or impaired neuromuscular transmission may develop worsening of the pre-existing disorder.

Refer to full SmPC for further information on overdose.

Special precautions for disposal and other handling
There have been reports of transient reactions including cough, oropharyngeal pain, headache, throat and eye irritation in healthcare professionals and caregivers accidentally exposed to the aerosolized product. To reduce the risk of unintended exposure, ARIKAYCE liposomal and the Lamira Nebuliser System should be used and maintained according to the instructions provided.

Refer to full SmPC for further information on special precautions for disposal and other handling

Legal Category
Prescription only medicine.

Pack quantities and costs
Pack-size of 28 vials. The carton also contains the Lamira Nebuliser Handset and 4 aerosol heads.
Price: POA

Marketing Authorisation Holder
Insmed Netherlands B.V.
Stadsplateau 7
3521 AZ Utrecht
Netherlands

Marketing Authorisation Number
EU/1/20/1469/001

Adverse events should be reported. Healthcare professionals are asked to report any adverse events involving ARIKAYCE LIPOSOMAL 590 MG via the HPRA Pharmacovigilance website's online reporting system at: www.hpra.ie. Alternatively, they can be emailed to the HPRA at medsafety@hpra.ie. Adverse events should also be reported to Insmed via safety@insmed.com

Additional information is available on the SmPC or from Insmed Medical Information at: medicalinformation@insmed.com

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