EMA/446084/2020
EMEA/H/C/005264

Arikayce liposomal (*amikacin*)

An overview of Arikayce liposomal and why it is authorised in the EU

What is Arikayce liposomal and what is it used for?

Arikayce liposomal is an antibiotic for treating adults with a lung infection caused by *Mycobacterium avium* complex (MAC), a group of bacteria commonly found in the environment, such as in soil and water. It is used in patients with limited treatment options who do not have cystic fibrosis.

Lung infection caused by MAC is rare, and Arikayce liposomal was designated an 'orphan medicine' (a medicine used in rare diseases) on 8 April 2014. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations eu3141259.

Arikayce liposomal contains the active substance amikacin.

How is Arikayce liposomal used?

The patient inhales Arikayce liposomal through the mouth once a day using a nebuliser (a machine for turning the medicine into a mist that the patient can breathe in). If tests show that the infection has cleared, the patient should continue using Arikayce liposomal for a further 12 months; however, if the infection shows no sign of clearing 6 months after starting treatment, the medicine should be stopped.

Arikayce liposomal is used together with other antibiotics. It can only be obtained with a prescription, and treatment should be started and managed by a doctor experienced in treating MAC lung infection. Prescribers should consider official guidance on the use of antibiotics.

For more information about using Arikayce liposomal, see the package leaflet or contact your doctor or pharmacist.

How does Arikayce liposomal work?

Amikacin is an antibiotic that belongs to the group 'aminoglycosides'. It works by disrupting the production of proteins that bacteria need to build their cell walls, thereby damaging the bacteria and eventually killing them. In this medicine, amikacin is contained in tiny fat particles known as liposomes, which allows the medicine to remain in the lung for longer.

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What benefits of Arikayce liposomal have been shown in studies?

A main study in 336 patients showed that Arikayce liposomal is effective at clearing lung infections caused by MAC. After 6 months of treatment, 29% of patients on standard care who used Arikayce liposomal tested negative for the infection, compared with 9% of patients on standard care alone. In addition, 3 months after stopping treatment, 55% of patients whose infections cleared with Arikayce liposomal continued to test negative. No patient who received standard care tested negative 3 months after stopping treatment.

What are the risks associated with Arikayce liposomal?

The most common side effects with Arikayce liposomal affect the lungs and airways: dysphonia (changes to the voice), cough, dyspnoea (difficulty breathing) and haemoptysis (coughing up blood) may affect more than 1 person in 10.

Other common side effects include pain in the mouth or throat, tiredness, diarrhoea, worsening of bronchiectasis (weakened, scarred airways and build-up of mucus) due to infection, nausea (feeling sick) and bronchospasm.

Arikayce liposomal must not be used in patients who are hypersensitive (allergic) to soya, to any aminoglycoside antibiotic or to any ingredient of this medicine. It must also not be used together with another aminoglycoside or in patients with severely impaired kidneys.

For the full list of side effects of Arikayce liposomal, see the package leaflet.

Why is Arikayce liposomal authorised in the EU?

The main study showed that Arikayce liposomal can clear MAC lung infection in some patients. Although the effect of Arikayce liposomal is modest, the medicine could benefit patients who have few treatment options. In terms of its safety, Arikayce liposomal can cause significant side effects, particularly during the first months of treatment. The Agency therefore recommended restricting the medicine to patients with limited treatment options.

The Agency concluded that the benefits of Arikayce liposomal outweigh its risks and that it can be authorised in the EU.

What measures are being taken to ensure the safe and effective use of Arikayce liposomal?

The company will provide patients taking the medicine with an alert card to inform them of the risk of allergic alveolitis (inflammation in the lungs due to an allergy).

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Arikayce liposomal have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Arikayce liposomal are continuously monitored. Side effects reported with Arikayce liposomal are carefully evaluated and any necessary action taken to protect patients.

Other information about Arikayce liposomal

Arikayce liposomal received a marketing authorisation valid throughout the EU on 27 October 2020.

Further information on Arikayce liposomal can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR arikayce-liposomal.

This overview was last updated in 10-2020.