

Package leaflet: Information for the patient

ARIKAYCE liposomal 590 mg nebuliser dispersion amikacin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ARIKAYCE liposomal is and what it is used for
2. What you need to know before you use ARIKAYCE liposomal
3. How to use ARIKAYCE liposomal
4. Possible side effects
5. How to store ARIKAYCE liposomal
6. Contents of the pack and other information
7. Instructions for use

1. What ARIKAYCE liposomal is and what it is used for

ARIKAYCE liposomal is an **antibiotic** that contains the active ingredient amikacin. Amikacin belongs to a group of antibiotics called aminoglycosides which stop the growth of certain bacteria that cause infections.

ARIKAYCE liposomal is used by inhalation to treat **lung infection** caused by *Mycobacterium avium* Complex in adults with limited treatment options who do not have cystic fibrosis.

2. What you need to know before you use ARIKAYCE liposomal

Do not use ARIKAYCE liposomal

- if you are allergic to **amikacin** or other **aminoglycosides, soya** or **any of the other ingredients** of this medicine (listed in section 6)
- if you are taking any other aminoglycosides (oral or for injection)
- if you have very poor kidney function

Warnings and precautions

Talk to your doctor or pharmacist before using ARIKAYCE liposomal if:

- you use a bronchodilator (“reliever”) for breathing problems, as you will be asked to use that first, before using ARIKAYCE liposomal;
- you have **kidney problems**; you may need to have a kidney test before starting treatment;
- you have **hearing difficulties, ringing or buzzing in the ears** (tinnitus) or **balance problems** including spinning sensation, lack of coordinated muscle movements, dizziness or light-headedness. You may have to have a hearing test before starting or during treatment, if you have any hearing problems;
- you suffer from **other lung diseases**;
- you have a disease that causes muscle weakness and fatigue, such as **myasthenia gravis**.

Talk to your doctor immediately if, whilst using ARIKAYCE liposomal you experience any of the below:

- loss of consciousness, skin rash, fever, worsening or new problems with your breathing;
- worsening of kidney problems;
- ear problems like ringing in your ears or loss of hearing.

See section 4.

Children and adolescents

ARIKAYCE liposomal should not be given to children and adolescents less than 18 years old.

Other medicines and ARIKAYCE liposomal

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Special care is needed if you are taking other medicines, as some could interact with ARIKAYCE liposomal, for example:

- diuretics (“water tablets”) such as ethacrynic acid, furosemide, or mannitol
- other medicines that can affect your kidneys, hearing, balance or reduce muscle strength

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, the use of ARIKAYCE liposomal should be avoided. Ask your doctor or pharmacist for advice before using this medicine.

If you become pregnant while using ARIKAYCE liposomal, inform your doctor. He will advise whether to stop using ARIKAYCE liposomal.

It is not known if amikacin passes into breast milk in humans. If you are breastfeeding, your doctor will advise you whether to stop breast-feeding or stop treatment with this medicine.

Driving and using machines

ARIKAYCE liposomal can cause dizziness and other vestibular disturbances, such as vertigo and balance disorders. You are advised not to drive or operate machinery while inhaling ARIKAYCE liposomal. If you have questions, please talk to your doctor.

3. How to use ARIKAYCE liposomal

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is **one vial** of ARIKAYCE liposomal inhaled in your mouth once a day, using the Lamira Nebuliser. After 6 months of treatment your doctor will advise whether to continue or to stop treatment. The maximum duration of treatment is 18 months.

Taking ARIKAYCE liposomal

If you use a bronchodilator (“reliever”), use that first, before using ARIKAYCE liposomal.

Each vial is **for single use only**.

- **Only use** ARIKAYCE liposomal with the Lamira Nebuliser Handset and aerosol head connected to a Lamira Control Unit. See section 7 for how to use the medicine together with the Lamira Nebuliser System.
- **Do not** use ARIKAYCE liposomal with any other type of handset or aerosol head.
- **Do not** put other medicines in the Lamira Nebuliser Handset.
- **Do not** drink the liquid in the vial.
- **Read the instructions** for use, which are provided at the end of this leaflet.

How and when do you replace the Lamira Nebuliser Handset?

One Lamira Nebuliser Handset should be used for one 28-day treatment course. The aerosol head should be replaced weekly. There are 4 aerosol heads provided in each ARIKAYCE liposomal carton. Please refer to the manufacturer's instructions for use for cleaning and storage advice.

If you use more ARIKAYCE liposomal than you should

Tell your doctor immediately if you are concerned that you may have used too much of this medicine.

If you forget to use ARIKAYCE liposomal

If you forget to take your medicine, take it as soon as possible on the day of the missed dose. Do not take more than one dose on the same day to make up for a forgotten dose.

If you stop using ARIKAYCE liposomal

You must tell your doctor if you decide to stop using ARIKAYCE liposomal for any reason.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if:

- you experience any hypersensitivity or severe allergic reactions when taking ARIKAYCE liposomal (e.g. with low blood pressure, loss of consciousness, severe skin rash or severe wheezing and breathlessness). The frequency of these side effects is not known.
- you experience worsening of your usual lung problems or new problems with your breathing (e.g. breathlessness or wheezing). This may be a sign of severe inflammation in the lungs that requires treatment and may mean you should stop taking ARIKAYCE liposomal. The frequency of these severe side effects is common to very common.

Other side effects:

Tell your doctor or pharmacist if you experience any of the following:

Very common side effects (may affect more than 1 in 10 people)

- Difficulty in speaking
- Difficulty in breathing
- Cough
- Coughing up blood

Common side effects (may affect up to 1 in 10 people)

- Infection causing worsening of your lung condition
- Increase in mucus coughed up from lungs
- Chesty cough
- Wheezing
- Throat irritation
- Sore throat
- Loss of voice
- Thrush (a fungal infection) in the mouth
- Pain in the mouth
- Change in your sense of taste
- Lung inflammation
- Headache
- Dizziness
- Feeling unsteady
- Diarrhoea
- Feeling sick (nausea)

- Being sick (vomiting)
- Dry mouth
- Decrease of appetite
- Itching of the skin
- Deafness
- Ringing in your ears
- Kidney problems including poor kidney function
- Joint pain
- Muscle pain
- Rash
- Tiredness
- Discomfort in chest
- Fever
- Loss of weight

Uncommon side effect (may affect up to 1 in 100 people)

- Anxiety

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ARIKAYCE liposomal

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze, discard any vial that has been frozen.

If the dose you want to use is refrigerated, remove the vial from the refrigerator and allow it to come to room temperature before using it.

Alternatively, ARIKAYCE liposomal can be stored at room temperature below 25 °C, but only for up to 4 weeks. Once at room temperature, any unused medicinal product must be discarded at the end of 4 weeks.

This medicine is a milky white liquid in a clear vial. Do not use if you notice change in colour or any small lumps floating in the vial.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ARIKAYCE liposomal contains

- The active substance is amikacin. 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.
- The other ingredients are cholesterol, dipalmitoylphosphatidylcholine (DPPC), sodium chloride, sodium hydroxide and water for injections.

What ARIKAYCE liposomal looks like and contents of the pack

ARIKAYCE liposomal is a white to off-white, milky nebuliser dispersion in a 10 mL glass vial sealed with a rubber stopper and a metal seal with a flip tear-off cap.

The 28 vials are provided in a carton for a 28-day supply; one vial per day. One ARIKAYCE liposomal carton contains 4 inner cartons, each containing 7 vials and one aerosol head. The 28-day supply pack also contains 1 Lamira Nebuliser Handset.

Marketing Authorisation Holder

Insmed Netherlands B.V.
Stadsplateau 7
3521 AZ Utrecht
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Manufacturer

Almac Pharma Services (Ireland) Ltd.
Finnabair Industrial Estate,
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Ireland

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>. There are also links to other websites about rare diseases and treatments.

7. Instructions for use

ARIKAYCE liposomal is for oral inhalation use with the Lamira Nebuliser System. Before using your Lamira Nebuliser System, be sure you read and understand the detailed information in the full Instructions for Use that come with the Lamira Nebuliser System. These will provide more complete information about how to put together (assemble), prepare, use, clean, and disinfect your Lamira Nebuliser System.

Wash your hands with soap and water and dry them well.

Assemble the handset including the connection to the controller as illustrated in the full Instructions for Use.

Preparing the medicine for use:

1. It is recommended that the vial be removed from the refrigerator at least 45 minutes before use to allow it to come to room temperature. Do not use other medicines in the Lamira Nebuliser Handset.
2. Shake the ARIKAYCE liposomal vial vigorously, until the medicine looks the same throughout and well mixed.
3. Lift orange cap from vial and put aside (Figure 1).

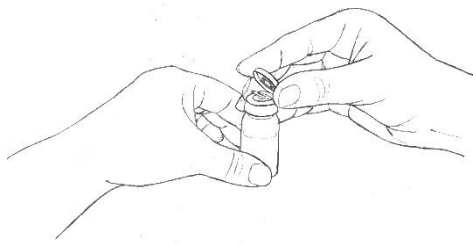


Figure 1

4. Grip the metal ring on top of the vial and pull it down gently until one side breaks away from the vial (Figure 2).

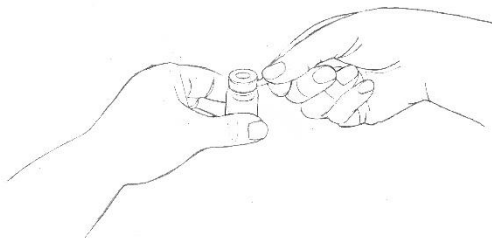


Figure 2

5. Pull the metal band from around the vial top in a circular motion until it comes off completely from the vial (Figure 3).

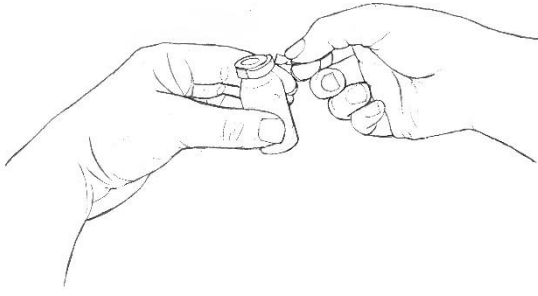


Figure 3

6. Put aside the metal ring after it is detached. Carefully remove the rubber stopper (Figure 4).

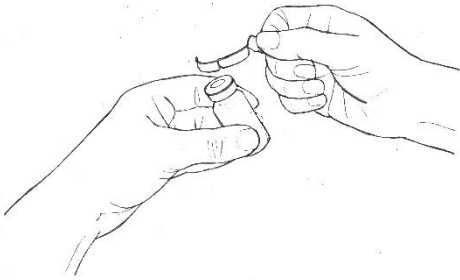


Figure 4

7. Pour the contents of the ARIKAYCE liposomal vial into the medicine's reservoir of the Lamira Nebuliser Handset (Figure 5).



Figure 5

8. Close the medication reservoir (Figure 6).



Figure 6

9. Sit in a relaxed, upright position. This makes inhaling easier and helps the medicine get into your lungs.

10. Insert the mouthpiece and take slow, deep breaths. Then, breathe normally in and out through the mouthpiece until your treatment is complete. Treatment should take about 14 minutes but could take up to 20 minutes. Be sure to hold the handset level throughout the treatment (Figure 7).

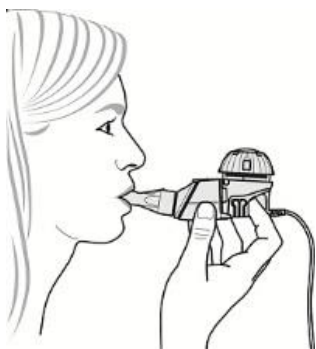


Figure 7