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# mResvia (*single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilised in the prefusion conformation)*

An overview of mResvia and why it is authorised in the EU

## What is mResvia and what is it used for?

mResvia is a vaccine for protecting against lower respiratory tract disease (diseases of the lungs such as bronchitis or pneumonia) caused by respiratory syncytial virus (RSV) in adults aged 60 years and older.

mResvia contains a molecule called messenger RNA (mRNA) with instructions for producing an RSV protein called membrane-anchored RSV-A glycoprotein F.

## How is mResvia used?

The recommended dose is one single injection into the muscle of the upper arm.

The vaccine can only be obtained with a prescription and should be used according to official recommendations issued at national level by public health bodies.

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

## How does mResvia work?

mResvia works by preparing the body to defend itself against RSV. It contains a molecule called mRNA which has instructions for making the RSV-A glycoprotein F. This is a protein on the surface of RSV-A (a subtype of RSV), which the virus needs to enter the body's cells.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the RSV-A glycoprotein F. The person's immune system will then recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it. This immune response will also recognise a similar protein called RSV-B glycoprotein F, which is found on the RSV-B subtype.

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If, later on, the person comes into contact with RSV, their immune system will recognise it and be ready to defend the body against it.

After vaccination, the mRNA from the vaccine is broken down and removed from the body.

## What benefits of mResvia have been shown in studies?

A main study involved over 35,000 adults aged 60 years and above who received either mResvia or a dummy injection. Around 4 months after vaccination, people who received mResvia had an 84% reduction in their risk of getting lower respiratory tract disease caused by RSV, compared with those who received a dummy injection. During this period, 9 out of 17,572 people who received mResvia got lower respiratory tract disease due to RSV with 2 or more symptoms compared with 55 out of 17,516 people who received a dummy injection.

Around 9 months after vaccination (by which time around 1,000 people more had joined the study), vaccination with mResvia was found to reduce the risk of RSV-associated lower respiratory tract disease by 63%. During this period, 47 out of 18,112 people vaccinated with mResvia got lower respiratory tract disease due to RSV with 2 or more symptoms compared with 127 out of 18,045 people who received the dummy injection.

## What are the risks associated with mResvia?

For the full list of side effects and restrictions with mResvia, see the package leaflet.

The most common side effects with mResvia (which may affect more than 1 in 10 people) include pain at the injection site, tiredness, headache, muscle pain and joint pain. These side effects are usually mild in intensity and resolve within 1 to 2 days after vaccination.

## Why is mResvia authorised in the EU?

The main study found that mResvia is effective at preventing lower respiratory tract disease due to RSV in older adults, although there is some uncertainty as to how long this effect will last. To address this uncertainty, the company that markets mResvia will provide long-term data on the effectiveness of the vaccine from the main study, as well as data from a study looking at the effect of revaccination after 12 and 24 months. It will also provide data on the safety and effectiveness of the vaccine in people who have an increased risk of developing lower respiratory tract disease due to RSV, including those who are immunocompromised (have a weakened immune system). The vaccine is generally well tolerated, with mild to moderate side effects that resolve within a few days.

The Agency therefore decided that mResvia's benefits are greater than its risks and that it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of mResvia?

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

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

## Other information about mResvia

mResvia received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on mResvia can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/mresvia

This overview was last updated in 08-2024.