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Abrysvo (*respiratory syncytial virus vaccine (bivalent, recombinant)*)

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

What is Abrysvo and what is it used for?

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

It is also for use in mothers during pregnancy to protect their infants against LRTD from birth through 6 months of age.

Abrysvo contains versions of two proteins found on the surface of the virus called RSV subgroup A stabilised prefusion F and RSV subgroup B stabilised prefusion F.

How is Abrysvo used?

The recommended dose is one single injection into the muscle of the upper arm. Pregnant individuals should receive the dose between weeks 24 and 36 of gestation.

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 Abrysvo, see the package leaflet or contact your doctor or pharmacist.

How does Abrysvo work?

Abrysvo works by 'teaching' the immune system (the body's natural defences) how to defend the body against a disease. Abrysvo contains proteins from the surface of the RSV virus. When a person is given the vaccine, the immune system treats the viral proteins as 'foreign' and makes defences against them. If, later on, the vaccinated person comes into contact with the virus, the immune system will recognise the viral proteins and be prepared to attack it. This will help to protect against LRTD caused by the virus.

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What benefits of Abrysvo have been shown in studies?

In a study in over 34,000 adults aged 60 years and above, people who received Abrysvo had a 67% reduction in their risk of getting LRTD caused by RSV compared with those who had a dummy injection. Of the 16,306 adults who received the vaccine, 11 developed severe RSV-LRTD, defined as LRTD with at least two or more lower respiratory symptoms of RSV, compared with 33 adults out of the 16,308 who received the dummy injection. In addition, 2 of those who received Abrysvo developed three or more symptoms of RSV-LRTD compared with 14 adults who received the dummy injection.

A second study in pregnant women showed that Abrysvo reduced the risk of RSV-LRTD by 51% in infants born to vaccinated mothers compared with those whose mothers received a dummy injection. Of 3,495 infants born to mothers vaccinated with Abrysvo, 57 developed RSV-LRTD within the first 6 months after birth, compared with 117 out of the 3,480 infants born to mothers who had a dummy injection.

What are the risks associated with Abrysvo?

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

The most common side effects (which may affect more than 1 in 10 people) with Abrysvo in people aged 60 years and above include pain at the vaccination site.

The most common side effects (which may affect more than 1 in 10 people) with Abrysvo in pregnant women at 24 to 36 weeks of gestation include pain at the vaccination site, headache and myalgia (muscle pain).

The majority of side effects were mild to moderate and resolved within a few days.

Why is Abrysvo authorised in the EU?

Abrysvo was shown to be effective at preventing RSV-LRTD in adults aged from 60 years as well as in infants born to vaccinated mothers for at least the first 6 months of life. There are no major safety concerns and the majority of side effects with Abrysvo were mild or moderate. The European Medicines Agency therefore decided that Abrysvo's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Abrysvo

Abrysvo received a marketing authorisation valid throughout the EU on 23 August 2023.

Further information on Abrysvo can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/abrysvo

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