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Kostaive (*zapomeran*)

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

What is Kostaive and what is it used for?

Kostaive is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and over.

Kostaive contains the active substance zapomeran, a self-amplifying messenger RNA (mRNA) molecule (known as sa-mRNA): this is a molecule with instructions for producing a protein from the original strain of SARS-CoV-2, the virus that causes COVID-19; it also has instructions for making an enzyme called replicase, which makes additional copies of the mRNA.

How is Kostaive used?

Kostaive is given as a single injection into the muscle of the upper arm. For people who have previously been vaccinated, Kostaive should be given at least 5 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to people with a severely weakened immune system.

Kostaive should be used according to official recommendations issued at national level by public health bodies.

For more information about using Kostaive, see the package leaflet or consult a healthcare professional.

How does Kostaive work?

Kostaive works by preparing the body to defend itself against COVID-19. Kostaive contains a molecule called sa-mRNA, which has instructions for making a copy of the SARS-CoV-2 spike protein. This is a protein on the surface of SARS-CoV-2 which the virus needs to enter the body's cells.

The sa-mRNA in Kostaive also has instructions for making an enzyme called replicase. When a person is given the vaccine, some of their cells will read the vaccine's sa-mRNA and temporarily make the replicase enzyme. The replicase will then make additional copies of the spike protein mRNA, which the

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cell uses to make the spike protein. The person's immune system will then identify the spike protein as foreign and produce natural defences — antibodies and T cells — against it.

If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on the virus and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, preventing its entry into the body's cells and destroying infected cells.

The vaccine is contained in lipid nanoparticles (small fat particles) that help the mRNA enter the body's cells.

The mRNA from the vaccine, the replicase enzyme and the spike protein are broken down after vaccination and removed from the body.

What benefits of Kostaive have been shown in studies?

Studies showed that Kostaive is effective at triggering the production of antibodies against SARS-CoV-2 and protecting people against COVID-19.

A first study measured the efficacy of Kostaive in over 15,000 adults with no known history of COVID-19 who were given either the vaccine or placebo (a dummy injection); people received 2 doses given 4 weeks apart. In the study, between 36 and 92 days after the first dose, the risk of experiencing symptomatic COVID-19 was 56.7% lower in people who had received the vaccine (200 out of 7,762 people had COVID-19 symptoms) than in people who had received placebo (440 out of 7,696 had COVID-19 symptoms). This means that the vaccine showed a 56.7% efficacy in the study.

The study also looked at the reduction in the number of severe cases of COVID-19: 2 out of 7,762 vaccinated people had severe disease, compared with 41 out of 7,696 people who had received placebo. This means that vaccine's efficacy against severe COVID-19 was 95.3%.

The vaccine was also compared with an authorised mRNA COVID-19 vaccine (Comirnaty) when given as a booster to people who had previously been vaccinated with an mRNA vaccine (Spikevax or Comirnaty). The results showed that the level of antibodies against the spike protein in people who received a booster dose of Kostaive was at least as high as that seen in people who received a booster dose of Comirnaty.

Can children be vaccinated with Kostaive?

Currently, Kostaive is not authorised in people below 18 years of age. The company has developed a plan to assess the vaccine in children at a later stage.

Can immunocompromised people be vaccinated with Kostaive?

Kostaive has not been studied in immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Can pregnant or breast-feeding women be vaccinated with Kostaive?

Animal studies do not show any harmful effects in pregnancy; however, data on the use of Kostaive in pregnant women are limited.

The decision on whether to use the vaccine during pregnancy should be made in close consultation with a healthcare professional after considering the benefits and risks.

Kostaive can be used during breastfeeding as levels of the mRNA and spike protein in breast milk are expected to be negligible.

Can people with allergies be vaccinated with Kostaive?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) may occur in people receiving the vaccine. Therefore, as for all vaccines, Kostaive should be given under close medical supervision, with the appropriate medical treatment available.

How well does Kostaive work for people of different ethnicities and genders?

The main study with Kostaive found that the efficacy of Kostaive and its safety profile are similar in men and women.

Although the main study was carried out in Vietnam and included mainly Asian people, an additional study included mostly white people and showed no differences in terms of side effects by ethnicity or country.

There is no reason to suggest that the immune response induced by Kostaive will vary across ethnicities.

What are the risks associated with Kostaive?

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

The most common side effects with Kostaive (which may affect more than 1 in 10 people) include pain and tenderness at the injection site, tiredness, headache, muscle and joint pain, chills, dizziness and fever. Most side effects are mild and disappear within a few days of vaccination.

Very rare cases of anaphylaxis (sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness) can also occur in up to 1 in 10,000 people.

Why is Kostaive authorised in the EU?

Kostaive has been shown to provide protection against COVID-19 when used as primary vaccination in people with no known history of COVID-19 and to trigger the production of antibodies against COVID-19 when used as a booster after vaccination with another mRNA vaccine. Although Kostaive targets the original strain of SARS-CoV-2, it provided relevant protection against the strain circulating at the time of the main study. In terms of safety, most side effects with Kostaive are mild and in line with those seen with mRNA vaccines.

The European Medicines Agency therefore decided that Kostaive’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 Kostaive?

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

A risk management plan (RMP) is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks.

Safety measures for Kostaive are implemented in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Kostaive provides regular reports on the safety and efficacy of the vaccine.

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

Other information about Kostaive

Kostaive received a marketing authorisation valid throughout the EU on 12 February 2025.

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

This overview was last updated in 01-2025.