



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Imvanex (*live modified vaccinia Ankara virus*)

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

What is Imvanex and what is it used for?

Imvanex is a vaccine used to protect against smallpox in adults. It contains an attenuated (weakened) form of the vaccinia virus called 'modified vaccinia virus Ankara', which is related to the smallpox virus.

Smallpox was officially declared eradicated in 1980, with the last known case of the disease occurring in 1977. This vaccine will be used when it is considered necessary to protect against smallpox in accordance with official recommendations.

Imvanex can also be used to protect adults from monkeypox and disease caused by the vaccinia virus.

How is Imvanex used?

Imvanex is given by injection under the skin, preferably in the upper arm. People who have not been previously vaccinated against smallpox, monkeypox or the disease caused by the vaccinia virus should receive two 0.5 ml doses, with the second dose given at least 28 days after the first.

If a booster dose is considered necessary in people previously vaccinated, a single 0.5 ml dose should be given. People with a weakened immune system (the body's natural defences) who require a booster should receive two doses, with the second dose given at least 28 days after the first.

The vaccine can only be obtained with a prescription. For more information about using Imvanex, see the package leaflet or contact your doctor or pharmacist.

How does Imvanex work?

Vaccines work by preparing the body to defend itself against a disease. When a person is given the vaccine, the immune system recognises the virus in the vaccine as 'foreign' and makes antibodies against it. When the person comes into contact again with similar viruses, these antibodies together with other components of the immune system will be able to kill the viruses and help protect against disease.

Imvanex prepares the body to defend itself against infection with the variola (smallpox), monkeypox and vaccinia viruses. It contains a weakened form of the vaccinia virus called 'modified vaccinia virus Ankara', a virus that is closely related to the smallpox and monkeypox viruses but does not cause disease in humans and cannot reproduce in human cells. Because of the similarity between the virus in

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Imvanex and these viruses, antibodies produced against it are expected to protect against monkeypox, smallpox and vaccinia.

What benefits of Imvanex have been shown in studies?

Imvanex was shown in studies to be effective at triggering the production of antibodies to a level expected to provide protection against smallpox.

Five main studies were carried out. The studies involved over 2,000 adults, including patients with HIV and atopic dermatitis (an itchy skin condition caused by an overactive immune system) and people who had been vaccinated against smallpox in the past. Two of the studies specifically looked at the effectiveness of Imvanex as a booster. A subsequent study in 433 people who had not been vaccinated before found that the level of protective antibodies after vaccination with Imvanex was at least as high as with a conventional smallpox vaccine. It is not yet known how long the protection will last.

Data from several animal studies showed protection against monkeypox in non-human primates vaccinated with Imvanex and then exposed to the monkeypox virus.

Imvanex is also expected to protect against the disease caused by vaccinia virus, since the vaccine is based on a modified version of vaccinia virus.

What are the risks associated with Imvanex?

The most common side effects with Imvanex (which may affect more than 1 in 10 people) are headache, nausea, myalgia (muscle pain), tiredness and injection site reactions (pain, redness, swelling, hardening and itching).

Imvanex must not be used in patients who are hypersensitive (allergic) to the active substance or any of the substances found at trace levels, such as chicken protein, benzonase and gentamicin.

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

Why is Imvanex authorised in the EU?

The European Medicines Agency considered that Imvanex is effective at triggering the production of antibodies against smallpox to a level that provides protection at least as high as that from conventional smallpox vaccines. The vaccinia virus in Imvanex cannot replicate in human cells and hence is less likely to cause side effects than conventional smallpox vaccines. Imvanex would therefore be beneficial for people who cannot be given vaccines containing replicating viruses, such as patients with a weakened immune system.

For the prevention of monkeypox, the Agency considered that the effectiveness of Imvanex could be inferred from animal studies. In addition, because of the similarity between the virus in Imvanex ('modified vaccinia virus Ankara') and the variola (smallpox), monkeypox and vaccinia viruses, antibodies produced against it are expected to protect against monkeypox, smallpox as well as the disease caused by vaccinia. The safety profile of Imvanex is considered favourable, with vaccinated people experiencing mild to moderate side effects. The Agency therefore decided that Imvanex's benefits are greater than its risks and it can be authorised for use in the EU.

Imvanex has been authorised under 'exceptional circumstances'. This is because it has not been possible to obtain complete information about Imvanex due to the rarity of the diseases. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Imvanex?

Since Imvanex has been authorised under exceptional circumstances, the company that markets Imvanex will provide data on the vaccine's benefits and risks from an observational study in people who are given the vaccine, if ever there is an outbreak of smallpox in the future.

The company will also collect data from an observational study that will be carried out during the ongoing monkeypox outbreak in Europe to confirm the effectiveness of the vaccine in protecting against monkeypox.

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

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

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

Other information about Imvanex

Imvanex received a marketing authorisation valid throughout the EU on 31 July 2013.

Further information on Imvanex can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/imvanex

This overview was last updated in 07-2022.