MVA-BN VACCINE IN RESPONSE TO MPOX (MONKEYPOX)

Information leaflet

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About this booklet

This booklet provides general information about the MVA-BN vaccine when it is used in response to MPOX (monkeypox).

It has information on:

- What is MPOX (monkeypox)?
- Risks of MPOX (monkeypox) infection?
- What is the MVA-BN vaccine and why is offered in response to MPOX (monkeypox)?
- Who is being offered this vaccine in response to MPOX (monkeypox)?
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- How do I report side effects?
- More information

Please read this leaflet carefully and keep it, as you may need to refer back to it.

Talk to your healthcare team if you have any questions about this vaccine.

Our aim for this information booklet is to allow you to make an informed decision about getting the vaccine

What is MPOX (monkeypox)?

MPOX (monkeypox) is a rare infection that is caused by the MPOX (monkeypox) virus. The risk of catching it in Ireland is very low. It is very uncommon to get MPOX (monkeypox) from someone else as it does not spread easily between people.

The biggest risk of spread between people is through close physical contact including sexual contact with someone who has MPOX (monkeypox).

It can also be spread between people by:

- touching clothing, bedding or towels used by someone with the MPOX (monkeypox) rash
- touching MPOX (monkeypox) skin blisters or scabs
- close proximity to the coughs or sneezes of a person with MPOX (monkeypox)
- It usually takes between 5 and 21 days from contact with an infected person for the first symptoms to appear.

The first symptoms of MPOX (monkeypox) include:

- fever (38 degrees Celsius or higher)
- headache
- exhaustion
- muscle aches
- backache
- swollen glands
- chills

A rash usually appears 1 to 5 days after the first symptoms. The rash often begins on the face, then spreads to other parts of the body. If MPOX (monkeypox) has been spread through sexual contact, the rash can appear around the mouth, lips, genitals and anal passage.

The rash can look like chickenpox. It starts as raised spots, which turn into small blisters filled with fluid. These blisters eventually form scabs which later fall off, although scarring can occur where the scabs have fallen off.

Risks of MPOX (monkeypox) infection?

The illness is usually mild and most people recover in 2 to 4 weeks.

However, MPOX (monkeypox) can cause serious illness. Sometimes, especially in people with a weak immune system, pregnant women or very young babies it can be a severe illness.

Complications of MPOX (monkeypox) infection can include pneumonia, sepsis (a life-threatening reaction to an infection), infection of the eye (leading to sight loss) and, inflammation of the brain (encephalitis).
MPOX (monkeypox) infection at times can be fatal.

What is the MVA-BN vaccine and why is offered in response to MPOX (monkeypox)?

A vaccine is a substance that should improve immunity (protection) to a particular infection. Vaccines teach the immune system how to protect people from diseases caused by these infections.

The MVA-BN vaccines are manufactured by the company Bavarian Nordic. These vaccine contains a ‘weakened’ version of the vaccinia virus (Modified Vaccina Ankara Bavarian Nordic Live virus; MVA-BN) which is related to the smallpox virus. The vaccines trigger your body to develop antibodies. These antibodies help fight the smallpox virus if it enters the body in the future. As MPOX (monkeypox) virus is very similar to the smallpox virus, studies have shown that the smallpox vaccine is also effective at protecting you from MPOX (monkeypox) virus too. Therefore, the antibodies this vaccine triggers are expected to offer protection against the MPOX (monkeypox) virus.

The MVA-BN vaccine called Imvanex® is licensed in Europe by the European Medicines Agency (EMA) to prevent disease caused by the smallpox, MPOX (monkeypox) and vaccinia viruses. Imvanex is currently licensed in the United States (called Jynneos) and Canada (called Imvamune) to prevent smallpox and also MPOX (monkeypox) disease in adults. Due to limited stocks of Imvanex, the EMA’s Emergency Task Force has recommended the Jynneos vaccine can be used in the European Union in response to MPOX (monkeypox) disease too.

Who is being offered this vaccine in response to MPOX (monkeypox)?

The vaccine can be offered:

1) **Before** exposure to MPOX (monkeypox) virus
People at high risk of exposure including gay, bisexual, men who have sex with men (gbMSM) and others at high risk of unprotected exposure.

2) **After** exposure to MPOX (monkeypox) virus
People who may have been in contact with people who have MPOX (monkeypox).

Not everyone who has been in contact with MPOX (monkeypox) virus needs this vaccine. The vaccine may be offered to close contacts based on the nature and proximity of their contact with someone infected with MPOX (monkeypox). Public health specialists will offer this vaccine after a risk benefit assessment.

Is the vaccine effective against MPOX (monkeypox)?

Data suggests that smallpox vaccination is 85% effective at preventing illness associated with MPOX (monkeypox) infection. This vaccine is effective at producing antibodies against smallpox therefore it is can be expected to offer protection against MPOX (monkeypox) too.

If the vaccine is used in people after they have been exposed to the MPOX (monkeypox) virus it is best to give the vaccine within four days of contact, as the vaccine may protect against illness associated with MPOX (monkeypox).

However, the vaccine can be given up to two weeks after contact with the MPOX (monkeypox) virus. While the vaccine may not prevent the illness, it may reduce serious symptoms.

Is the vaccine safe?

We are still learning about how well the vaccine protects against MPOX (monkeypox) and about its side-effects.

The vaccine is approved by the EMA for use in Europe in adults (aged 18 and over) to prevent disease from the smallpox, MPOX (monkeypox) and vaccinia viruses.

The National Immunisation Advisory Committee in Ireland has recommended that this vaccine can be used to protect people from MPOX (monkeypox).

The safety of this vaccine has been tested in over 20 clinical trials which involved more than 5,000 individuals.

We have limited information on the use of this vaccine, for example in children and pregnant women.

Recently many countries started using the MVA-BN vaccines to prevent MPOX (monkeypox) disease.

All medicines have side effects and you should read about known common and rare side effects of this vaccine in this leaflet before you give consent to be vaccinated.

Can the vaccine cause MPOX (monkeypox) or smallpox?

No. The vaccine contains a weakened form of the virus that cannot cause disease in humans. It is likely to cause fewer side effects than other smallpox vaccines and may be used in people who have a weak immune system.

How is this vaccine given?

The vaccine can be given in two ways:
This vaccine can be given as an injection **under the skin** (subcutaneous) in the upper arm.

For people 18 years of age and older, it can also be given as an injection **between the layers of the skin** (intradermally) on the forearm or upper arm. This will allow more people to be vaccinated but more people may also experience side effects.

The European Medicines Agency and the National Immunisation Advisory Committee in Ireland have recently advised that the vaccine can be given between the layers of the skin whilst there is a shortage of vaccine, to ensure as many people as possible can be vaccinated.

How many doses of the vaccine will I need?

People who are given this vaccine before exposure to MPOX (monkeypox) should get two doses 28 days apart if they have never received a smallpox vaccine before. Dose intervals of less than 4 weeks should be avoided.

People who are recommended to get this vaccine because they have been exposed to MPOX (monkeypox) usually only need one dose. If you have never received a smallpox vaccine before you may be offered a second dose 28 days later if you are likely to continue having contact with MPOX (monkeypox).

Previous smallpox vaccine is protective against MPOX (monkeypox). However, smallpox vaccine was discontinued in 1972 in Ireland. People under the age of 50 will not have had the smallpox vaccine. If you have received a smallpox vaccine before you only need 1 dose of the vaccine unless you have a weak immune system, when you need two doses.

How long does it take the vaccine to work?

You will be offered a course of this vaccine (one or two doses).

After finishing the recommended course of this vaccine most people will have immunity. This means they should be protected against MPOX (monkeypox). It takes 14 days after completing your course of this vaccine for it to work.

It is expected that the body's response to the vaccine will be similar whether it is given under the skin (subcutaneously) or between layers of the skin (intradermal).

There is a chance you might still get MPOX (monkeypox) illness, even if you have had the vaccine, particularly if you receive it more than four days after contact with the disease, but it may reduce any symptoms of MPOX (monkeypox) disease.

What are the side effects of the vaccine?

Like all medicines, vaccines can cause side effects. Most of these are mild to moderate, short-term, and not everyone gets them. Most of the side effects are similar in frequency after the first or second dose whether the vaccine is given under the skin or between the layers of skin.

More than 1 in 10 people will have these very common side effects:

- headache
- muscle aches
- nausea
- tiredness
- side effects where the vaccine was given (pain, redness, swelling, hardness or itching).

If your vaccine is given between layers of skin (intradermally) it is very common to notice a small lump or a change in the colour of your skin where the vaccine was given. This can last for several months.
This is very common after people have had a second dose.

What are the side effects of the vaccine?

Up to 1 in 10 people will have these common side effects:

- fever or chills
- joint pain
- pain in hand and feet
- loss of appetite
- side effects where the vaccine was given (lump, discolouration, bruising or warmth)

Up to 1 in 100 people will have these uncommon side effects:

- nose and throat infection,
- upper respiratory tract infection
- swollen lymph nodes
- abnormal sleep
- dizziness
- abnormal skin sensations
- muscle stiffness
- sore throat
- runny nose
- cough
- diarrhoea
- vomiting
- rash
- itch
- skin inflammation
- side effects where the vaccine was given (bleeding and irritation)
- underarm swelling
- feeling unwell
- flushing
- chest pain
- increase of cardiac biomarkers (like Troponin I)
- increased liver enzyme
- decreased white blood cell count
- decreased mean platelet volume

Up to 1 in 1,000 people will have these rare side effects:

- pain in the armpit
- sinus infection
- influenza and influenza like illness
- conjunctivitis
- hives
- skin discolouration
- sweating
- skin bruising
- night sweats
- lump in skin
- back pain
- neck pain
- muscle spasms
- muscle pain

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What are the side effects of the vaccine?

Up to 1 in 1,000 people will have these rare side effects:

- muscle weakness
- swelling of the hands and feet
- fast heartbeat
- ear and throat ache
- abdominal pain
- dry mouth
- vertigo
- migraine
- nerve disorder causing weakness, tingling or numbness
- drowsiness
- side effects where the vaccine was given(scaling, inflammation, abnormal skin sensation, reaction, rash, numbness, dryness, movement impairment and vesicles- a small fluid-filled sac)
- weakness
- swelling of the face, mouth and throat
- increased white blood cell count
- bruising

Are there some people who should not get the vaccine?

Yes. You should not get the vaccine if you have had a serious allergic reaction to any of the ingredients in the vaccine (including chicken protein, benzonase, gentamicin, ciprofloxacin and Trometamol).

You should not receive the vaccine between layers of skin if you have a history of keloid scar formation, but you may still receive the vaccine under the skin.

Read the manufacturer's Patient Information Leaflet to see the full list of ingredients.

When can people get a MVA-BN vaccine after a COVID-19 vaccine?

You can get your MVA-BN vaccine at any time after your COVID-19 vaccine.

When can people get a COVID-19 vaccine after their MVA-BN vaccine?

As a precaution NIAC has advised that you should leave four weeks (or 28 days) after getting the MVA-BN vaccine before you get your COVID-19 vaccine because of the unknown risk of myocarditis (an inflammatory condition of the heart).

Can people with eczema (atopic dermatitis) get the vaccine?

People with eczema (atopic dermatitis) may get more side effects after vaccination.

7 in 100 people with eczema who receive the vaccine may experience a flare-up of their eczema.

Can you get the vaccine if you have a high temperature?

No. If you have a fever (temperature of 38 degrees Celsius or above), you should delay getting the vaccine until you feel better (unless the risks outweigh the benefits).

Can you get the vaccine if you have a weak immune system?

Yes. The vaccine can be used in people with a weak immune system (including people living with HIV). The doctor will discuss this with you before you get the vaccine. However, the vaccine may not work as well for you.

Can you get the vaccine if you are pregnant or breastfeeding?

There is no evidence that the vaccine is unsafe if you're pregnant, as the vaccine doesn't reproduce in human cells. **There is limited data on the use of this vaccine in pregnant women.** No safety concerns have been identified for them or their babies. MPOX (monkeypox), however, can cause serious illness in pregnant women, and can result in infection of an unborn baby and stillbirth.

You can get the vaccine if you are breastfeeding. The vaccine dose not reproduce in human cells but it is not known if the vaccine is excreted in breast milk.

We are still learning about this vaccine. If you are pregnant or breastfeeding, you should talk to a doctor about the risks and benefits of this vaccine and the risks of MPOX (monkeypox).

Can children (under the age of 18) receive this vaccine?

The vaccine is not approved in children under the age of 18. We are still learning about this vaccine in children. The safety and how well this vaccine works in children is not known. Similar vaccines have been used in children as young as 5 months in clinical trials. The side effects in children are expected to similar to that in adults.

Children are at increased risk of severe illness from MPOX (monkeypox).

Parents or legal guardians will need to consent for children aged under 16 before they can receive the vaccine. If a child (under the age of 18) is being offered the vaccine, the risk and benefits of the vaccine and the risk of MPOX (monkeypox) will be discussed with the young person and their family beforehand.

Anyone aged under 18 years will be offered the vaccine under the skin (subcutaneously).

How do I report side effects?

As with all vaccines, you can report suspected side effects to the Health Products Regulatory Authority (HPRA).

The HPRA is the regulatory authority in the Republic of Ireland for medicines, medical devices and other health products. As part of its role in the safety monitoring of medicines, the HPRA operates a system through which healthcare professionals or members of the public can report any suspected adverse reactions (side effects) associated with medicines and vaccines which have occurred in Ireland.

The HPRA strongly encourages reporting of suspected adverse reactions (side effects) associated this vaccines to support continuous monitoring of their safe and effective use. To report a suspected adverse reaction to this vaccine, please visit www.hpra.ie/report

You can also ask your Doctor or a family member to report this for you. As much information as is known should be provided, and where possible, the vaccine batch number should be included.
The HPRA cannot provide clinical advice on individual cases. Members of the public should contact their healthcare professional with any medical concerns they may have.

More information

For more information, read the manufacturer's Patient Information Leaflet. This will be printed for you prior to getting the vaccine, or you can find it on www.ema.europa.eu/en/medicines/human/EPAR/imvanex

You can also talk to a health professional, like your GP (Doctor), or your healthcare team.

You can also visit the HSE website at www.hse.ie/conditions/monkeypox/