MVA-BN vaccine in response to mpox

Information Leaflet

PROTECT PREVENT IMMUNISE

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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.

It has information on:

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- How do I report side effects?
- Where can I get 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?

Mpox is a rare infection that is caused by the mpox virus. The risk of catching it in Ireland is very low. It is uncommon to get mpox 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.

It can also be spread between people by:

- touching clothing, bedding or towels used by someone with the mpox rash
- touching mpox skin blisters or scabs
- being in close proximity to the coughs or sneezes of a person with mpox

It usually takes between 2 to 4 weeks from contact with an infected person for the first symptoms to appear.

The first symptoms of mpox 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 has been spread through sexual contact, the rash can appear around the mouth, lips, genitals and anal passage. Some people may only get a rash in the genital and anal areas.

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.

The symptoms of mpox generally last for 2 to 4 weeks.

Are there different types of mpox infection?

There are two clades (strains) of mpox virus, called clade I and clade II. In 2022, in Ireland and internationally, there was an outbreak of cases of clade II mpox. In this outbreak, most (but not all) cases were in men who self-identified as gay, bisexual and men who have sex with men (gbMSM). People who were at high risk of infection were offered vaccination. In August 2024, an international public health emergency was declared because of an outbreak of clade I mpox in Africa. Clade I mpox can cause a more serious mpox infection, and infection may spread more easily between individuals. In the current outbreak in Africa, infection has spread among people living in the same household and also through sexual contact. Infection has also spread in healthcare settings in situations where it is assumed that appropriate personal protective equipment (PPE) was not worn.

What are the risks of mpox infection?

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

However, mpox (clade I or clade II infection) can cause serious illness. Sometimes, especially in people with a weak immune system, pregnant women or very young babies, mpox can cause severe illness.

Complications of mpox 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 infection at times can be fatal.

Clade I mpox can cause more serious infections than clade II mpox.

What is the MVA-BN vaccine and why is it being offered in response to mpox?

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 particular infections.

The MVA-BN vaccines are manufactured by the company Bavarian Nordic. These vaccines contain 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 virus is very similar to the smallpox virus, studies have shown that the smallpox vaccine is also effective at protecting you from mpox virus too. Therefore, the antibodies this vaccine triggers offer protection against the mpox virus.

Two MVA-BN vaccines are available in the European Union (EU). Imvanex® is licensed in Europe by the European Medicines Agency (EMA) to prevent disease caused by the smallpox, mpox and vaccinia viruses in those aged 12 years and older. Jynneos is licensed in the United States to prevent smallpox and also mpox in adults. The EMA's Emergency Task Force recommend that the Jynneos vaccine can be used in the EU in response to mpox.

Who is being offered the MVA-BN vaccine in response to mpox?

The vaccine can be offered before or after exposure to mpox.

1: Before exposure to mpox the vaccine may be offered to:

(i) People at high risk of mpox exposure including gay, bisexual, men who have sex with men (gbMSM), sex workers and others at high risk of unprotected mpox exposure.

(ii) Healthcare and laboratory staff who may be in contact with mpox may be recommended to receive the vaccine following a health and safety risk assessment.

(iii) People who may be travelling to areas currently affected by clade 1 mpox outbreaks and will have close contact with people in affected communities following a discussion with their healthcare provider.

2: After exposure to mpox the vaccine may be offered to:

(i) People who are unvaccinated who have been in contact with people who have mpox

(ii) People who were vaccinated against mpox more than two years ago

Not everyone who has been in contact with mpox virus needs this vaccine. The vaccine may be offered to close contacts who are at high risk of infection based on the nature and proximity of their contact with someone infected with mpox. Public health specialists may recommend the MVA-BN vaccine after a risk benefit assessment.

Is the MVA-BN vaccine effective against mpox?

This vaccine is effective at producing antibodies against smallpox therefore it offers protection against mpox too. Data suggest that vaccination is 82% effective at preventing illness associated with clade II mpox if two doses are given before exposure to mpox. There are less data available about how effective the vaccine is at preventing clade I illness, but it is expected to be similar.

If the vaccine is used in people after they have been exposed to the mpox virus it may protect against illness associated with mpox. It is best to give the vaccine within four days of contact.

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

Is the MVA-BN vaccine safe?

The MVA-BN vaccine (Imvanex) is approved by the EMA for use in Europe in individuals aged 12 years and older to prevent disease from the smallpox, mpox and vaccinia viruses.

The MVA-BN vaccine (Jynneos) is authorised by the FDA in the USA and is distributed in the European Union and used in Ireland for prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or mpox infection.

The National Immunisation Advisory Committee in Ireland has recommended that the MVA-BN vaccine can be used to protect people from mpox.

The safety of the MVA-BN vaccine is closely monitored. The most common adverse events (side effects) reported are injection site pain, redness, swelling and tiredness, headache, and muscle aches and pains.

There is less information available about the use of this vaccine in children aged < 12 years or in pregnant or breastfeeding women, however, no specific safety concerns have been identified. You should speak to your healthcare provider about the benefits and risk of vaccination and the risk of mpox infection and illness before you give consent for you or your child to be vaccinated.

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 MVA-BN vaccine cause mpox or smallpox?

No. The MVA-BN 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 the MVA-BN vaccine given?

The vaccine can be given in two ways:

(i) This vaccine can be given as an injection under the skin (subcutaneous) in the upper arm.

(ii) 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. For example, redness, swelling and itching at the site where the vaccination is given and some people have reported skin discolouration at the injection site which lasted for six or more months.

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 MVA-BN vaccine will I need?

To complete a primary vaccination course, people who are given this vaccine **before exposure to mpox** should get two doses four weeks apart if they have never received a smallpox vaccine before.

Previous smallpox vaccine is protective against mpox. 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 one dose of the vaccine unless you have a weak immune system. If you have a weak immune system, you will need two doses as your primary vaccination course.

People who are recommended to get this vaccine **because they have been exposed to mpox** may only need one dose. However, if you may have ongoing exposure to mpox and you have never received a smallpox vaccine before you may be offered a second dose four weeks after your first dose to complete your primary vaccination course.

If I am exposed to mpox and MVA-BN vaccination is recommended, when should I get the vaccine?

Getting the MVA-BN mpox vaccine within four days of exposure may prevent the onset of mpox symptoms. If the vaccine is given within 5 to 14 days after the date of last exposure, it may reduce the symptoms of mpox but it may not prevent the disease.

There is no evidence that vaccination beyond 14 days from exposure has any benefit. However vaccination beyond 14 days could be considered in those who are severely immunocompromised after discussion with their specialist medical team.

Will I need a MVA-BN booster vaccination?

Mpox booster vaccination is not currently recommended in those who have completed the primary vaccination course.

However, if a person who was vaccinated over two years ago is exposed to mpox again, public health specialists may recommend a booster vaccine after a risk benefit assessment. The decision to recommend a MVA-BN booster vaccination will be based on when the exposure to mpox occurred and on the nature and proximity of the contact with someone infected with mpox. Getting the MVA-BN mpox vaccine within four days of exposure may prevent the onset of mpox symptoms.

How long does it take the MVA-BN vaccine to work?

After finishing the recommended primary course of the MVA-BN mpox vaccine (one or two doses), most people will have immunity. This means they should be protected against mpox. 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 illness, even if you have had the vaccine, particularly if you receive it more than four days after contact with the disease, but being vaccinated may reduce any symptoms of mpox.

What are the side effects of the MVA-BN vaccine?

Like all medicines, vaccines can cause side effects. Not everyone will get side effects from the MVA-BN mpox vaccine. If people do get side effects, most side effects will be mild to moderate and will resolve within seven days following vaccination. 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.

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)

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.

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

- muscle weakness
- swelling of the hands and feet
- fast heartbeat
- ear and throat ache
- 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 MVA-BN 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 the MVA-BN vaccine after the COVID-19 vaccine?

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

When can people get the MVA-BN vaccine before or after an influenza vaccine?

You can get your MVA-BN vaccine at any time before or after your influenza vaccine.

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

As a precaution NIAC has advised that you should leave four weeks 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 MVA-BN 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 MVA-BN 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 MVA-BN 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 MVA-BN vaccine if you are pregnant or breastfeeding?

There is no evidence that the vaccine is unsafe if you are pregnant, as the vaccine does not reproduce in human cells. There are limited data on the use of this vaccine in pregnancy however no safety concerns have been identified for them or their babies. Mpox however, can cause serious illness in pregnancy, and can result in infection of an unborn baby and stillbirth.

You can get the vaccine if you are breastfeeding but it is not known if the vaccine is excreted in breastmilk.

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.

Can children under the age of 18 years receive the MVA-BN vaccine?

The MVA-BN vaccine (Imvanex) can be given to children and adolescents aged 12 years and older. This has been approved by the European Medicines Agency (EMA). The vaccine provides similar protection in children and adolescents aged 12 years and older as it does in adults and no additional safety concerns have been identified in children and adolescents.

Parents or legal guardians will need to consent for children aged under 16 years before they can receive the vaccine. Children are at increased risk of severe illness from mpox. 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 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).

Can children under the age of 12 years receive the MVA-BN vaccine?

The vaccine is not currently approved in children aged less than 12 years. We are still learning about this vaccine in young children. Similar vaccines have been used in children as young as 5 months in clinical trials. The side effects in children aged under 12 years are expected to be similar to that in adults.

Parents or legal guardians will need to consent for children aged under 16 before they can receive the vaccine. Children are at increased risk of severe illness from mpox. 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 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 of the MVA-BN vaccine 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 with 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 suspected adverse reactions 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.

Where can I get more information?

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/mpox/