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Monkeypox Vaccine

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Introduction

In response to cases of monkeypox that have been identified in Ontario, vaccine against monkeypox is being offered to specific populations with the goal of limiting ongoing transmission, and a priority focus on communities at high risk of exposure and protecting vulnerable groups.[1]

This document is intended for health care providers and public health partners. It provides an overview of Imvamune, the monkeypox vaccine authorized for use in Canada. This document will be updated as new information becomes available.

Key Messages

- **You cannot get smallpox or monkeypox from poxvirus-derived vaccine:** The viral vector used in Imvamune vaccine, MVA-BN, is non-replicating and is therefore unable to cause smallpox or monkeypox infection.[2,3]

- **Imvamune has a favourable safety profile compared to previous generations of smallpox vaccines:** The most commonly reported adverse events at the injection site following receipt of Imvamune were pain, redness, swelling, induration (hardness), and pruritus (itching). The most commonly reported systemic adverse events were fatigue, headache, myalgia (muscle aches), arthralgia (joint pain), fever, chills, nausea, and loss of appetite. Most adverse events reported following receipt of Imvamune were of mild to moderate in intensity and resolved within the first seven days following vaccination.[4,5]

Background

Smallpox is caused by the variola virus, which belongs to the poxvirus family, genus *Orthopoxvirus*. Other members of this genus that can infect humans are monkeypox virus, cowpox virus, and vaccinia virus.[4]

The World Health Assembly declared smallpox eradicated in 1980 due to the success of global vaccination with replication-competent vaccinia virus (VACV) based vaccines.[2,6] However, these second-generation smallpox vaccines were contraindicated for use in several populations including immunocompromised persons and individuals with atopic dermatitis. For this reason, there have been multiple attempts to produce an attenuated smallpox vaccine.[2,7]

Imvamune is a third-generation smallpox vaccine produced by Bavarian Nordic.[3,4]

- Modified vaccinia Ankara (MVA) is derived from a strain of the poxvirus, Chorioallantois Vaccinia virus Ankara (CVA), following attenuation through over 500 continuous passages in primary chicken embryo fibroblasts.[2]

- Imvamune is developed from Modified Vaccinia Ankara–Bavarian Nordic (MVA-BN), a proprietary and patented viral vector vaccine platform technology that is a further attenuation of the MVA strain.[2,8] This method leads to a substantial loss of the genome which encodes immune evasion and virulence factors.[2,7,3]

- Imvamune is a live attenuated, non-replicating vaccine. It demonstrates low neuropathogenicity in human and animal studies, while retaining immunogenic properties, including demonstrable protective immune responses against a variety of orthopoxviruses.[2,3] As *Orthopoxvirus* infections are cross-protective against other viruses within the genus, Imvamune vaccine will similarly provide cross-protection against both smallpox and monkeypox.[5,9,10]

- In Canada, Imvamune is the first, and currently the only, vaccine approved for use against monkeypox.[4]

MVA-BN was developed primarily for use as a viral vector in a variety of vaccine types and is a platform that has been adapted to address a wide variety of other infectious diseases, including Mvabea (MVN-BN Filo), a vaccine against Ebola which is currently licensed by the European Medicines Agency (EMA) under exceptional circumstances, and MVA-BN RSV, currently in clinical trials for the treatment of respiratory syncytial virus (RSV).[2,8,11]

Use of Imvamune Against Monkeypox

Imvamune was initially authorized for use in Canada on November 21, 2013, as an Extraordinary Use New Drug Submission (EUNDS) for use by the Canadian Government in an emergency situation for active immunization against smallpox infection and disease in persons 18 years of age and older who have a contraindication to the first or second generation smallpox vaccines.[4] It was subsequently approved under a supplement to the EUNDS on November 5, 2020 for active immunization against smallpox, monkeypox and related *Orthopoxvirus* infections and disease in adults 18 years of age and older determined to be at high risk for exposure.[4]

In response to the current outbreak in Ontario, Imvamune is currently being offered for the purposes of pre-exposure prophylaxis (PrEP) to specific populations, including individuals who are immunocompromised, pregnant, currently engaging in or planning to engage in sex work, or any individual with recent risk factors who self-identifies or has sexual partners who self-identify as belonging to the gay, bisexual, and other men who have sex with men (gbMSM) community.[1] Household and/or sexual contacts of those identified for PrEP eligibility who are moderately to severely immununocompromised or pregnant may be considered for PrEP and should contact their healthcare provider or local public health unit (PHU) for more information.[1]

Imvamune is also being offered throughout Ontario for the purposes of post-exposure prophylaxis (PEP) to those who have been assessed by their local PHU to be a high risk contact to monkeypox.[1] Intermediate risk contacts may also be offered PEP following PHU assessment of an individual's risks and benefits.[1]

For more details on indications for use of Imvamune in Ontario, see the Ministry of Health's (MOH) Monkeypox Vaccine (Imvamune) Guidance for Health Care Providers.[1]

Table 1: Characteristics of a MVA-BN (Imvamune) vaccine authorized for use in Canada

Trade Name	Imvamune
Manufacturer	Bavarian Nordic A/S[4,5]
Other trade names	Jynneos (US)[12], Imvanex (Europe)[7]
Vaccine Platform	Modified Vaccinia Ankara-Bavarian Nordic (live attenuated, non-replicating)[4,5]
Authorized Ages for Use	18 years and older[4,5]
Off-label Use	Post-exposure prophylaxis may be considered for children who have been determined to have had a high risk exposure.[4]
Dosage	0.5 mL supplied as a liquid frozen suspension in a 2 mL glass vial containing a MVA-BN titer of at least 0.5 x 10^8 Inf.U/0.5 mL (Inf.U = infectious units)[5]
Adjuvant	No[5]
Diluent	No
Potential allergens	Traces of residual host (egg) cell DNA and protein Tromethamine (trometamol, Tris) Benzonase Gentamicin and ciprofloxacin[4]
Schedule	Post-exposure prophylaxis: 1 dose[1,a,b] Pre-exposure prophylaxis: 1 dose[1,b]
Co-administration with other vaccines	The administration of Imvamune for PEP should not be delayed in an individual who has recently received another vaccine.[1] As data on co-administration of Imvamune and other vaccines are not available, it is recommended to not co-administer Imvamune with other vaccines, and wait for a period of at least 14 days between administration of Imvamune and another live or inactivated vaccine.[1] If timing can be planned and as a precautionary approach, it is recommended that Imvamune be given at least 4 weeks after or before an mRNA vaccine for COVID-19 due to the unknown risk for myocarditis/pericarditis with Imvamune.[4]
Route of Administration	Subcutaneous (SC)[4,5]

Trade Name	Imvamune
Storage Conditions[c]	Keep frozen at -25°C to -15°C. Do not re-freeze once thawed. Once thawed, vaccine may be used immediately or kept at +2°C to +8°C for up to 2 weeks prior to use. Do not use after expiration date shown on the vial label. Protect from light.[4,5]

[a] For the purposes of PEP, a single dose of the vaccine should be offered ideally within 4 days (up to 14 days) from the date of the last exposure to individuals who are a high risk contact of a confirmed or probable case of monkeypox.
[b] At this time, most individuals eligible for PreP or PEP are being offered a single dose of Imvamune. Moderately to severely immunocompromised individuals are eligible to receive two doses. Research laboratory employees working directly with replicating orthopoxviruses are eligible to receive two doses if there is an ongoing risk of exposure.
[c] For further information on storage and handling conditions, see the MOH's Imvamune Vaccine Storage and Handling Guidance

Mechanism of Action and Immune Response

MVA-BN effectively infects mammalian cells, which results in transcription of the viral genes, but virus is not released from the cells due to a genetic block in the viral assembly and egress.[2]

Vaccinia antigens are expressed at high levels, resulting in both humoral (antibody) and cellular (T-cell) immune responses, although the immunological mechanisms of protection against monkeypox are not fully understood.[2,7]

- Serological and cell-mediated responses to Imvamune and protection from disease outcomes have been demonstrated across different animal models; however, it remains unclear the degree to which preclinical results will predict outcomes in humans.[4]

Advantages and Limitations

Major advantages of Imvamune are that it can be administered to immunocompromised persons, and its favourable safety profile.[2,3,9] This is in contrast to first and second generation replication-competent smallpox vaccines, which have been associated with severe adverse events including generalized or progressive vaccinia, vaccinia keratitis, post-vaccinial encephalitis, and acute myopericarditis.[3,13] Additionally, live vaccinia virus of older generation smallpox vaccines could be inadvertently transferred from the site of immunization to other body sites (e.g., eyes, nose, genitalia) or to other persons.[2,13]

A limitation of Imvamune is that, due to its restricted use, there are limited post-marketing vaccine safety data; however, this data will accumulate over time.

Efficacy and Safety

MVA-BN efficacy studies were aimed at understanding its protective efficacy against smallpox; however, clinical efficacy was inferred from animal model challenge studies with monkeypox virus, indicating an overall protective effect.[3,5]

Clinical data for Imvamune in the context of PrEP is limited to clinical immunogenicity or indirect protection from vaccinia virus used in earlier generation smallpox vaccines.[4]

- A phase 3 efficacy trial found that immune responses (binding antibodies and neutralization antibodies) following two doses of Imvamune vaccine (at week 0 and week 4) were detectable by week 2, and at week 6, peaked at or beyond responses compared to a one dose of the second-generation replicating smallpox vaccine, ACAM2000.[9]

- The same trial also found that subjects who received Imvamune followed by ACAM2000 had an accelerated healing time and attenuated "take" caused by vaccinia virus, demonstrating that Imvamune is able to suppress the viral replication induced by ACAM2000, providing evidence of the efficacy of Imvamune to protect against smallpox.[9] However, clinical protection from symptoms of vaccinia infection may not be indicative of protection against monkeypox.[4]

There are very little data indicating the efficacy or effectiveness of Imvamune against monkeypox infection or disease in the context of PEP.[4] Clinical data for Imvamune PEP can be inferred from clinical pre-exposure testing where immunological responses were detected within 2 weeks of vaccination.[3] The optimal timing of PEP may be inferred from studies of early generation smallpox vaccines; however, it is unknown how these smallpox studies directly relate to protection from monkeypox by Imvamune.[4]

- Prior to 2022, there has been very limited real-world experience using Imvamune as PEP. In the UK, it was used previously in two instances in response to several cases of imported monkeypox.[3]

    - Following an exposure in 2018, the vaccine was offered as post-exposure vaccination to 17 community contacts with 29% (5 individuals) uptake. There was no onward transmission identified among the community contacts. Imvamune was also offered to 147 occupational contacts with 85.8% (126 individuals) uptake; following PEP, one case of monkeypox was identified in a health care worker who received vaccine 6 to 7 days after initial exposure.[3]

    - After a separate monkeypox exposure in 2019, 17 of 18 contacts accepted post-exposure vaccination and no onward transmission.[3]

There are limited data on long-term immunogenicity of Imvamune beyond 24 months following primary vaccination of vaccinia-naïve individuals with Imvamune.[4]

- In phase 2 clinical testing, immune responses after one or two doses of Imvamune declined after 2 years. One or two doses of Imvamune boosted previously generated immune responses within 7 days to the level of those achieved after the 2 dose primary series. There is no established threshold above which immune responses to any orthopoxviruses are considered protective, therefore the interpretation of the decline or boosting of immune responses remains unclear.[4]

Imvamune's safety has been assessed in 20 completed clinical trials where approximately 13,700 vaccine doses were given to 7,414 subjects, demonstrating a safety profile consistent with other licensed, modern vaccines.[2,5]

- The most common local adverse events following immunization (AEFI) were pain, erythema, induration and swelling. The most common systemic AEFIs were fatigue, headache, myalgia, and nausea. Most of the reported AEFIs were of mild to moderate intensity and resolved within the first seven days following vaccination.[4,5]

- 1.4% (91/6640) of Imvamune recipients, 2.1% (16/762) of Imvamune recipients who were smallpox vaccine-experienced, and 0.2% (3/1206) of placebo recipients who were smallpox vaccine-naïve reported cardiac adverse events of special interest. Among these were 28 with

asymptomatic post-vaccination elevation of troponin-I and 6 cases that were considered causally related to Imvamune vaccination. None of these 6 events were considered serious. There were no confirmed cases of myocarditis, pericarditis, endocarditis, or any other type of cardiac inflammatory disease.[4,5]

- Safety data from clinical testing do not identify any safety signals of concern; however, these data are limited and does not have sufficient power to identify very rare events.[4]

Use in Special Populations

Data on the use of Imvamune is very limited for populations who may be at risk for more severe outcomes from monkeypox infection, or may be at higher risk for adverse events due to vaccination.[4] Given that Imvamune is non-replicating, it is not associated with the same types of adverse events associated with previous generation smallpox vaccines.[4,2,7]

For most individuals who have been exposed to monkeypox or who have been identified to be at risk of monkeypox infection, the risks of the disease are greater than the risks from the vaccine.[14] When offering Imvamune to eligible individuals, informed consent should include a discussion of the benefits and potential risks given the current limited data on the effectiveness and safety of the vaccine, including off-label use if applicable, particularly among special populations.

Immunocompromised Individuals

Clinical trials of Imvamune have included small numbers of people living with human immunodeficiency virus (HIV) with a CD4 count ≥100 and hematopoietic stem transplant (HSCT) patients two years post-HSCT.[4,5] The safety profile was comparable to healthy controls in these populations. Although there is limited data on vaccine efficacy/immunogenicity or safety in immunocompromised populations, their risks of negative outcomes due to monkeypox infection is greater due to their immunosuppression.[4] Live vaccines are typically contraindicated for immunocompromised populations; however, Imvamune may safely be used due to its inability to replicate.[4,3]

Pregnant and Breastfeeding Individuals

There are very limited data on the use of Imvamune in pregnancy. No clinical trials have been conducted in pregnant individuals, although approximately 300 pregnancies have been reported to the manufacturer with no safety issues identified.[4,3,15] As well, animal models have shown no evidence of fetal harm. Pregnant individuals may be at risk for severe outcomes from monkeypox, including fetal death.[4,15] Other orthopoxvirus infections, such as variola virus (smallpox), result in worse outcomes in pregnant compared to non-pregnant women.[15] Although there is limited data on safety and efficacy of Imvamune in this population, there is no theoretical reason at this time that vaccination would have any adverse impact on the pregnant individual or the fetus. Live vaccines are typically contraindicated in this group, but Imvamune may be used due its inability to replicate.[4,3,15]

Lactating individuals are not at higher risk for negative outcomes due to monkeypox infection.[4] There is no data on whether the vaccine is excreted in breastmilk, although this is unlikely as the vaccine is non-replicating.[4,15]

Children and Youth < 18 years old

Imvamune has not been studied in persons under 18 years of age and is not authorized for use in this age group.[4,5] Although there is a lack of evidence of safety and efficacy of Imvamune, this population may be at higher risk of severe outcomes from monkeypox infection and may benefit from vaccination. Clinical trials with children have studied other vaccines (TB and malaria) using MVA as a viral vector with a reassuring safety profile.[4,3,5] Imvamune has also been provided to children as PEP in previous United Kingdom (UK) monkeypox incidents.[3] Imvamune may be considered for off-label use as PEP in this age group following a discussion of risks and benefits.[1]

Individuals with Atopic Dermatitis

Individuals with atopic dermatitis may be at high risk of severe monkeypox disease.[4,14] They may have more frequent and more intense reactions after receiving Imvamune, including transient worsening of atopic dermatitis symptoms.[4,5] This population was specifically studied in clinical trials as those with a history or presence of atopic dermatitis are contraindicated to receive previous generations of smallpox vaccine due to the risk of diffuse vaccinia virus.[12] Imvamune does not carry the same risk because of its inability to replicate.

History of myocarditis/pericarditis linked to a previous dose of live smallpox vaccine and/or Imvamune

First and second generation (replicating) smallpox vaccines have been associated with myocarditis and/or pericarditis, and although Imvamune is a non-replicating vaccine, there is a theoretical risk of myopericarditis following immunization given the uncertain etiology of myopericarditis associated with replication-competent smallpox vaccines.[7,5,16]

For individuals with a history of myocarditis/pericarditis linked to a previous dose of live replicating 1st or 2nd generation smallpox vaccine and/or Imvamune, the benefit of post-exposure immunoprophylaxis to protect against infection versus the risk of recurrent myocarditis should be discussed, and a precautionary approach is warranted until more information is available.[4]

Adverse Event Reporting

Any adverse event following Imvamune vaccine should be reported to the local public health unit using the PHO AEFI Reporting Form.[17] For additional information, please see PHO's Fact Sheet –Adverse Event Following Immunization Reporting for Health Care Providers in Ontario.[18]

Additional Information

For more information on monkeypox and Imvamune in Ontario, see:

- Ministry of Health: Monkeypox Vaccine (Imvamune) Guidance for Health Care Providers
- Ministry of Health: Recommendations for the Management of Cases and Contacts of Monkeypox in Ontario
- Ministry of Health: Imvamune Vaccine Storage and Handling Guidance
- Public Health Ontario: Epidemiological Summary of Monkeypox in Ontario.[1,19-21]

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