

MVA-BN (Modified Vaccinia Ankara – Bavarian Nordic) smallpox and mpox vaccine

Interim Guidance
27 November 2024



Target audience of this document: Individuals involved in mpox vaccine deployment and vaccination activities.

Overview

The MVA-BN (live Modified Vaccinia Ankara) vaccine is a third-generation smallpox vaccine, which contains a virus that cannot replicate in humans. The virus used in the vaccine is attenuated through multiple passages in non-human cells (i.e. in chicken embryo fibroblast cells) leading to a substantial loss of its virulence while retaining its immunogenic properties. As the MVA-BN vaccine cannot replicate in mammalian cells, it does not produce a lesion at the site of vaccination and has an improved safety profile. This makes it a preferred product in individuals for whom standard replicating vaccine (i.e. ACAM2000) and minimally replicating vaccine (i.e. LC16m8) are contraindicated or not recommended.

Vaccination with MVA-BN is recommended by the WHO Strategic Advisory Group of Experts (SAGE) in the context of an outbreak for persons at high risk of exposure to mpox (including contacts of cases); and in non-outbreak settings for primary preventive vaccination for laboratory personnel working with orthopoxviruses.¹ Recommendations for broader preventive use in non-outbreak setting will require further epidemiologic and vaccination related evidence. The non-replicating MVA-BN vaccine is manufactured by Bavarian Nordic A/S in the same site under the three licensed vaccine brands: Jynneos®, Imvamune® and Imvanex®.² WHO SAGE vaccination recommendations apply to all three brands.

According to the manufacturer, MVA-BN vaccine is administered as a two-dose subcutaneous injection given 4 weeks apart. When given prior to mpox exposure, two full doses (0.5 mL per dose) administered subcutaneously with an interval of 28 days is estimated to provide a vaccine effectiveness of 82% (95% CI: 72–92%).³ One full dose of vaccine administered subcutaneously is estimated to provide a vaccine effectiveness of 76% (95% CI: 64–88%). Further, one study shows that two fractional doses (e.g. 0.1 mL per dose) of vaccine administered intradermally with an interval of 28 days provided a vaccine effectiveness of 80.3%.³ When used as post-exposure in the context of sexual transmission, vaccine effectiveness of 20% (95% CI: -24–65%) was estimated during the global outbreak linked to Clade 2b and concerned the use of MVA-BN among gay, bisexual or other men who have sex with men.³ A person vaccinated with MVA-BN will develop maximum immunity against mpox 2 weeks after receiving the second dose. There are limited data on the duration of protection of two full dose administration. WHO SAGE recommends two doses to provide protection for individuals who have not previously received the vaccine. However, in the context of supply-constrained outbreak situations and based on the risk profile and the available vaccine data, off-label use of a single dose or intradermal fractional dosing of MVA-BN vaccine is recommended.¹

Manufactured by: Bavarian Nordic A/S, Kvistgaard, Denmark.

¹ [WHO Smallpox and mpox \(orthopoxviruses\) vaccine position paper](#)

² Manufacturing site is located in Kvistgaard, Denmark.

³ [Vaccine effectiveness of 3rd generation mpox vaccines against mpox and disease severity: a systematic review and meta-analysis - PubMed \(nih.gov\)](#)

Regulatory authorizations

Date of United States Food and Drug Administration (US-FDA) full authorization: 24 September 2019, for use of Jynneos® to individuals 18 years old and older who are at risk of smallpox or mpox infection.

Date of US-FDA Emergency Use Authorization (EUA): 9 August 2022, for the extension of the administration of Jynneos® subcutaneously to individuals less than 18 years of age.

Date of Health Canada full authorization: 5 November 2020, for use of Imvamune® to adults aged 18 years old and older, and immunocompromised individuals. Public Health Agency of Canada (PHAC), based on a benefit-risk assessment, issued its position paper on 24 May 2024 to include pregnant and lactating women, children and youth under 18 years old who are at risk of smallpox and mpox infection.

Date of European Medicines Agency (EMA) authorization: 21 July 2022, for use of Imvanex®, with age extension for 12–17 years of age on 19 September 2024.

Date of WHO Prequalification (PQ): 13 September 2024, for use of Imvanex®, with age extension to 12–17 years of age on 8 October 2024, with EMA as the reference authority.

Product characteristics

Presentation	Frozen, preservative-free suspension for injection in vials
Number of doses	Single dose vials (one dose 0.5 mL)
Vaccine syringe and needle type/size	Full dose: <ul style="list-style-type: none">Auto-disable (AD) syringes: 0.5 mLNeedle for subcutaneous injection: 23G to 25G Fractional dose (off-label use): <ul style="list-style-type: none">Auto-disable (AD) syringes: 0.1 mLNeedle for intradermal injection: 26G or 27G

Schedule and administration

Indication and age recommendation	Based on currently available evidence, WHO SAGE recommended the use of MVA-BN vaccine in the context of an mpox outbreak for persons at high risk of exposure to mpox. Large-scale mass vaccination is not recommended as a first response to an outbreak. While MVA-BN is currently not licensed for persons under 12 years of age, from a policy perspective this vaccine may be used off-label ⁴ in infants and children as per WHO SAGE and national recommendations and authorizations as relevant. This means MVA-BN vaccine use is recommended by WHO SAGE for all ages in outbreak settings when the benefits of vaccination outweigh the potential risks. ⁵ In August 2022, US-FDA granted emergency use authorization (EUA) for the subcutaneous administration of Jynneos® in persons under 18 years of age determined to be at high risk for mpox infection. In May 2024, PHAC, based on a benefit-risk assessment, issued its position paper on the use of Imvamune® in children and youth under 18 years old who are at risk of smallpox and mpox infection. In October 2024, based on the EMA approval on 19 September 2024, WHO Prequalification extended the age indication for individuals 12 years of age
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⁴ WHO SAGE or National Immunization Technical Advisory Groups (NITAG)/equivalent body policy recommendations that differ from the manufacturer label use indications then leads to off-label public health use of a vaccine. Explanatory note on off-label vaccine use: <https://www.who.int/publications/m/item/off-label-vaccine-use--explanatory-note-for-countries>

⁵ WHO Smallpox and mpox (orthopoxviruses) vaccine position paper

	<p>and older for Imvanex®.⁶ On November 2024, the EMA Emergency Task Force (ETF), taking into account the currently limited options for the prevention of mpox in the paediatric population and the safety data of Imvanex® and MVA-based vaccines reported so far in different age groups, published a recommendation on the use of Imvanex® for the prevention of mpox in children below 12 years of age who are at risk of mpox disease during the current international public health emergency.⁷ Although this does not constitute a formal regulatory authorization, EMA's ETF statement is in line with the WHO SAGE policy recommendation.</p> <p>Vaccination should be considered for high-risk individuals regardless of history of previous smallpox vaccination (documented previous smallpox vaccination and/or visible smallpox vaccine scar). For individuals previously vaccinated with mpox vaccines, an individual benefit-risk assessments should be done.</p>
Recommended number of doses/schedules	<p>Option 1: Two full doses (0.5 mL per dose) administered subcutaneously at a recommended interval of at least 28 days (4 weeks):</p> <p style="padding-left: 40px;">Dose 1: date of first dose</p> <p style="padding-left: 40px;">Dose 2: at least 28 days (4 weeks) after the first dose.</p> <p>Two doses are recommended to provide protection for individuals who have not previously received the vaccine. If the second dose is inadvertently missed or delayed, another visit should be arranged at the earliest opportunity to complete the primary schedule. In this case, the first dose should not be repeated.</p> <p>In the context of limited supply, other options could be considered:</p> <p>Option 2 (off-label use): Two fractional doses (0.1 mL per dose) administered intradermally at a recommended interval of at least 28 days for individuals older than 18 years.</p> <p>Option 3 (off-label use): One full dose (0.5 mL) administered subcutaneously.</p>
Booster dose	The duration of protection of mpox vaccines is not fully characterized and the need for booster dose has not been established. Periodic revaccination (every 2 to 5 years) should be considered for laboratory personnel working with more virulent orthopoxviruses and at high risk of exposure.
Route and site of administration	<p>Full dose: Subcutaneous administration</p> <p>Preferred site: the fatty tissue over the triceps area in the upper arm.</p> <p>Fractional dose (off-label use): Intradermal administration</p> <p>Preferred site: deltoid area of the upper arm or inner side of the forearm.</p>
Volume per dose	<p>Full dose: 0.5 mL per dose (each dose is supplied in a single-dose vial).</p> <p>Fractional dose (off-label use): 0.1 mL per dose (each single-dose vial provides 4-5 fractional doses).</p>
Diluent	Not applicable
Mixing syringe	Not applicable

⁶ The change in the labelled age indication for the administration of Imvanex® to children aged 12 years and above was approved by the EMA on 19 September 2024 and by the WHO Prequalification Team on 8 October 2024. Currently, the labelled age indication for Jynneos® and Imvamune® is 18 years of age and older. Therefore, their administration to individuals under 18 years old is considered “off-label” use until the manufacturer changes the label per approval of relevant authorities.

⁷ EMA ETF statement on the use of Imvanex® for the prevention of mpox in children below 12 years of age, 12 November 2024: https://www.ema.europa.eu/en/documents/other/etf-statement-use-imvanex-prevention-mpox-children-below-12-years-age_en.pdf

Preparation and vaccine administration	<p>Thawing a frozen vaccine:</p> <ul style="list-style-type: none"> • Bring out the number of frozen vials required for the session to ambient temperature up to 25 °C and allow vaccine to thaw. Thawing takes about 5–10 minutes. • Once thawed, keep the unopened vials in a vaccine carrier with coolant packs.⁸ • Do not refreeze thawed vaccine. <p>Vaccine administration:</p> <ol style="list-style-type: none"> 1. During a vaccination session, keep the thawed vaccine at +2 °C to +8 °C in a vaccine carrier with coolant packs. 2. Check the printed/mark expiration date on label. 3. Thawed vaccine is ready to use. Do not dilute. 4. Swirl the vaccine vial gently for at least 30 seconds. Do not shake. 5. Visually inspect the vial to make sure that the liquid is a milky, light yellow to pale white coloured suspension, free of particulate matter. If discoloured or containing any particulate matter, do not administer and safely discard the vial. 6. Draw up the appropriate dose of the vaccine from the vial just before administration. <p style="padding-left: 40px;">Full dose: 0.5 mL, or</p> <p style="padding-left: 40px;">Fractional dose (off-label use): 0.1 mL.</p> <ul style="list-style-type: none"> • DO NOT pre-load the vaccine in syringes. <ol style="list-style-type: none"> 7. Administer the vaccine immediately after loading the syringe as the MVA-BN vaccine has no preservatives. <p style="padding-left: 40px;">Full dose: subcutaneous, or</p> <p style="padding-left: 40px;">Fractional dose (off-label use): intradermal.</p> <p>Considerations:</p> <ul style="list-style-type: none"> • If fractional dose administration is implemented, unused doses should be discarded 6 hours after opening or at the end of the immunization session, whichever comes first.
Contraindications	<ul style="list-style-type: none"> • Known history of hypersensitivity to any component of the vaccine or to previous dose of MVA-BN.
Precautions	<ul style="list-style-type: none"> • All eligible individuals should be vaccinated under health care supervision, with the appropriate medical treatment available in case of allergic reactions. • As a standard precaution, observe the vaccine recipient for at least 15 minutes post-vaccination to detect and treat anaphylaxis.⁹ • Vaccination of people suffering from acute febrile conditions, should be postponed until they are afebrile and acute illness has improved. • Co-administration with other vaccine products has not been studied.
Special population groups	<ul style="list-style-type: none"> • While MVA-BN is currently not licensed for persons under 12 years of age, this vaccine may be used off-label in infants and children as per WHO SAGE

⁸ Use the appropriate coolant packs based on ambient temperature and type of vaccine carrier used. See: [Vaccine management handbook: how to use passive containers and coolant-packs for vaccine transport and outreach operations and Guidance on selecting, commissioning and using freeze-preventative vaccine carriers](#)

⁹ The symptoms and signs of an acute allergic reaction will generally occur between 5 and 60 minutes after vaccination and usually within 15 minutes: [Brief overview of anaphylaxis as an adverse event following immunization \(AEFI\) and practical guidance on its identification, case management and response in a primary care setting](#)

	<p>and national recommendations as relevant.¹⁰ This means vaccine use is recommended for all ages in outbreak settings where the benefits of vaccination outweigh the potential risks.</p> <ul style="list-style-type: none"> For pregnant and breastfeeding women, where consideration is given to vaccination, MVA-BN may be used as per WHO SAGE and national recommendations as relevant. The use of MVA-BN in pregnancy and breastfeeding constitutes an “off-label” use.¹⁰ For immunocompromised individuals, where consideration is given to vaccination, MVA-BN should be used as per WHO SAGE and national recommendations as relevant. Immunocompromised persons include those with active cancer, transplant recipients, immunodeficiency, active treatment with immunosuppressive agents, and people living with HIV with a current CD4 cell count of < 200 cells μl.
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Stability and storage

Vaccine storage temperature	<p>The MVA-BN vaccine may be delivered frozen at -25 °C to -15 °C or -50 °C or -80°C.</p> <p>At central and subnational stores:</p> <ul style="list-style-type: none"> If delivered frozen at -50 °C or -80 °C, keep the vaccine in ultra-low temperature (ULT) freezer, if available, to maximize its shelf life. If a ULT freezer is not available or the vaccine is delivered frozen at -20 °C, keep the vaccine frozen in a freezer at -25 °C to -15 °C to maximize its shelf life. <p>At health service facilities:</p> <ul style="list-style-type: none"> If the vaccine is delivered frozen at -20 °C and a vaccine freezer is available, store the vaccine in the freezer at -25 °C to -15 °C and use within the printed expiration date. If the vaccine is delivered thawed, or delivered frozen but no vaccine freezer is available, store the vaccine in a vaccine refrigerator at +2 °C to +8 °C. Use the vaccine before the end of the shelf life (up to 8 weeks from the thawing date) in this storage condition but not exceeding the printed expiration date. <p>Considerations:</p> <p>If thawed vaccine is not for immediate use:</p> <ul style="list-style-type: none"> Make sure to indicate on the carton or vial label the date the vaccine is moved from the freezer to the refrigerator to thaw. Keep the thawed unopened vaccine vial refrigerated at +2 °C to +8 °C and use it within 8 weeks from the date it was thawed but not beyond the original expiration date. Always check the vaccine’s remaining shelf life before distribution and administration.
Diluent storage temperature	Not applicable
Shelf life at different temperatures	<p>Frozen vaccine stored at ultra-low temperature:</p> <ul style="list-style-type: none"> Frozen at -80 °C +/-10 °C: 9 years Frozen at -50 °C +/-10 °C: 5 years <p>Frozen unopened vaccine stored in vaccine freezer at -25 °C to -15 °C: 3 years.</p>

¹⁰ Explanatory note on off-label vaccine use: <https://www.who.int/publications/m/item/off-label-vaccine-use--explanatory-note-for-countries>

	Thawed unopened vaccine stored in a refrigerator at +2 °C to +8 °C: 8 weeks from the date the vaccine was thawed and within the printed expiration date. ¹¹
Freeze sensitivity	Never refreeze a vaccine vial once it has been thawed.
Light sensitivity	Store in the original package protected from light.
Multi-dose vial policy	Administered as full single dose: Not applicable. Administered as fractional dose (off-label use): Discard unused doses in a vial after 6 hours of opening or at the end of the immunization session, whichever comes first.
Wastage rates	Dependent on country context.
Buffer stock needed	Dependent on country context.

Labelling and packaging

Vaccine vial monitor (VVM)	None
Secondary packaging dimension and volume	<p>A. Carton of 10 single-dose vials (10 doses) Dimensions: 3.8 x 5.4 x 9.3 cm.</p> <p>B. Carton of 20 single-dose vials (20 doses) Dimensions: 4.5 x 9.7 x 12.6 cm.</p>
Cold chain volume in secondary packaging	<p>A. 19.08 cm³/dose</p> <p>B. 27.50 cm³/dose</p>
Tertiary packaging dimension	<p>A. Box containing 48 secondary cartons (480 vials/480 doses) Dimensions: 12.4 cm x 24.6 cm x 39.2 cm.</p> <p>B. Box containing 70 secondary cartons (1400 vials/1400 doses) Dimensions: 26.4 cm x 33.1 cm x 49.7 cm.</p>

Safety information

Possible adverse events following immunization	<p>The most common local reactions include injection site pain, redness, swelling, headache, fatigue and nausea. Reactions are less severe and less frequent after the second dose. Serious adverse events to anticipate include febrile seizures and anaphylaxis. Health workers should also anticipate and be prepared for immunization stress-related responses (ISRR).</p> <p>During clinical trials, in individuals previously vaccinated with smallpox the reported reactions were generally mild, with local reactions such as redness and pain being the most frequent. In HIV-infected individuals, the adverse reactions were comparable to those in non-HIV-infected individuals. Individuals with atopic dermatitis reported reactions similar to those without atopic dermatitis. However, those with atopic dermatitis may experience more intense local skin reactions (such as redness, swelling and itching) at the injection site, and other general symptoms (such as headache, muscle pain, feeling sick or tired), as well as a flare-up or worsening of their skin condition.</p> <p>There were also reports of Crohn's disease, sarcoidosis, muscle paresis and throat tightness. Cardiac adverse events of special interests (AESIs) were</p>
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¹¹ The extension of shelf life to 8 weeks at +2 °C to +8 °C storage received WHO Prequalification approval for all three brands of MVA-BN on 13 September 2024.

	<p>reported in 1.3% of vaccine-naïve individuals and 2.1% of vaccine-experienced individuals. Six cases (0.08%) of cardiac AESIs were considered causally related to the vaccine, including tachycardia and abnormal ECG results, but none were serious.</p> <p>Post-marketing safety observations of the vaccine include reports of cases of myocarditis and pericarditis, hypersensitivity reactions like angioedema, rash, and urticaria, cases of facial paralysis/Bell's palsy (Imvanex®), dizziness and syncope, and injection site reactions such as warmth and vesicles.</p>
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Important reminders/other important information

MVA-BN is a non-replicating vaccine and cannot cause smallpox or mpox infections.

Since optimal levels of immunity require two doses of vaccine, encourage a vaccine recipient to complete the vaccination series. Vaccination records must be kept carefully because vaccination with MVA-BN does not produce a visible skin lesion and a scar. Without a written record, health workers will not be able to detect if a person has received the initial dose of vaccine.

Despite the reported reactions following immunization, the benefits of vaccination outweigh the risks. As with all injectable vaccines, appropriate medical treatment and supervision should always be available to treat rare cases of anaphylactic reactions following the administration of the vaccine. Ensure an adverse event following immunization (AEFI) response kit is available at the service point.¹²

WHO Global Advisory Committee in Vaccine Safety (GACVS) has highlighted the need for a collaborative approach to pool data from various countries to achieve a comprehensive understanding of vaccine safety and also to address the identified gaps in safety data on mpox vaccines, particularly for children, pregnant women, the immunocompromised, and AESIs resulting in hospitalization or death. Therefore, AEFI data submission to WHO global database is encouraged. For active safety surveillance in resource-limited countries, standardized data collection by vaccinators is recommended by adapting the WHO master cohort event monitoring protocol.

Never administer the MVA-BN vaccine intravascularly.

Any unused vaccine vial or waste material should be disposed of in accordance with local requirements. There is no need for a specific designation as bio-hazardous waste as the vaccine does not contain a live virus that can cause infections.

Syringes used for vaccination should be disposed of in a puncture-resistant safety box, in accordance with local regulations and guidance.

Counselling information

- Inform the vaccine recipient of the importance of completing the two-dose vaccination series unless one full dose regimen is implemented.
- Inform the vaccine recipient that the vaccine does not contain a live virus and cannot cause smallpox or mpox.
- Inform the vaccine recipient that despite the reported reactions, the benefits outweigh the risks of vaccination with MVA-BN.
- Advise vaccine recipient to report any adverse events to their health care provider or country's existing vaccine adverse event reporting system.

¹² Details are available in the document: [Brief overview of anaphylaxis as an adverse event following immunization \(AEFI\) and practical guidance on its identification, case management and response in a primary care setting](#)

Guidance development methods

This vaccine explainer was developed based on the existing technical documents such as the smallpox and mpox (orthopoxviruses) WHO position paper (August 2024); published journals; MVA-BN brands product inserts; and existing technical mpox resources from WHO and the United States Centers for Disease Control and Prevention (US-CDC). Relevant WHO and external subject matter experts were consulted and contributed during the development. Partners supporting country mpox emergency response activities also reviewed and provided inputs on this document.

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Drafting and editorial team: Maricel de Quiroz-Castro, Alba Vilajeliu.

Contributors:

WHO headquarters: Jhilmil Bahl, Madhava Ram Balakrishnan, Donald Joseph Brooks, Jorge Castilla-Echenique, Carmen Rodriguez Hernandez, Alexandra Hill, Joachim Maria Hombach, Ann Lindstrand, Benedict Millinchip, Ryoko Miyazaki-Krause, Katherine O'Brien, Elisabeth Pluut, Judith Van Holten, Alice Wimmer.

WHO regional offices: Reena Hemendra Doshi, Claude Mangobo, Harou Moussa, Charles Shey Umaru Wiysonge (WHO Regional Office for Africa) and Khanal Sudhir (WHO Regional Office for South-East Asia).

Reviewers:

PATH: Ben Creelman, Steven Diesburg, Tara Herrick, Courtney Jarrahian, Clara Orndorff, Manjari Quintanar Solares.

UNICEF: Chinara Israilova, Imran Mirza, Ann Ottosen.

PATH has FENSA clearance and is an eligible contributor to developing this vaccine explainer.

Declaration of interests

The external subject matter experts completed a declaration of interest. WHO reviewed each of these and concluded that none could give rise to a potential or reasonably perceived conflict of interest related to the subject covered by this technical product.

Plans for updating

This guidance is valid for 1 year after the date of publication, unless revised earlier. Triggers for an earlier update include but are not limited to the following factors: availability of new evidence pertaining to the use of this vaccine, any changes in regulatory approval or licensing, and any update on the product characteristics. WHO will monitor the situation closely for any changes that may affect this vaccine explainer.

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