Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 “KMB” Vaccination Procedure Guideline

English Ver. 2.1

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Version: 2.1

A. Before vaccination

Vaccination availability
・Persons at risk of exposure to Mpox ・Certain health workers at risk of repeated exposure; laboratory personnel working with orthopoxviruses; clinical laboratory and health care personnel performing diagnostic testing for Mpox; and outbreak response team members*. ・Persons who have been in close contact with a person diagnosed with Mpox within 14 days*. *According to the WHO Guidance on Vaccines and Immunization for Mpox published on November 16, 2022, an appropriate second or third-generation smallpox vaccine should be inoculated within 4 days of exposure to the Mpox virus (within 14 days if no symptoms are present).
Precautions when in contact with persons eligible for vaccination
・Healthcare workers should check persons who are in close contact with those diagnosed with Mpox within 14 days with/without signs and symptoms of suspected Mpox infection before being inoculated with dry cell culture varicella vaccine LC16 "KMB"(hereafter called LC16m8). ・If the onset of Mpox is suspected, healthcare workers should not inoculate with LC16m8. The priority should be to be diagnosed with Mpox. In addition, if the person is not adequately evaluated for diagnosis, treat the person by following the same infection control measures for patients with Mpox.
Persons who are not in an appropriate condition to receive LC16m8
(1) Persons with high fever. (2) Persons suffering from a severe acute illness. (3) Persons with a history of anaphylaxis caused by a vaccine ingredient. (4) Patients with a disease with clearly abnormal immune function or who are receiving immunosuppressive treatment (e.g. those who are taking adrenocortical steroids or immunosuppressive drugs). If healthcare workers inoculate persons who have been diagnosed with HIV with LC16m8, make sure a CD4 count is 200 cells/μL or above. There is no clear safety evidence for inoculating HIV patients with a CD4 count below 200 cells/μL with LC16m8(refer to the "Interactions" section of the package insert). (5) Patients who are pregnant. (6) Persons suffering from a proliferative skin disease that may be worsened by vaccine inoculation. (7) Besides those listed above, persons with inappropriate conditions for inoculating with vaccinations.
Required items for vaccination
・Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 “KMB”. ・Provided diluent (water for injection with 20 vol% glycerin). ・Sterilized bifurcated needle. ・Sterilized syringe (for a total volume of 0.5 mL to dissolve the vaccine).

・Sterilized injection needle (for a total volume of 0.5 ml to dissolve the vaccine).
・Alcohol swabs.
・Sharps container.
・Disposal container for medical waste.
・Medication tray.
・Light-shielding cover for medication.
・PPE as needed.
・Vaccination of persons before exposure: follow standard precautions.
・Vaccination of persons post-exposure: gown, face shield, gloves, and N95 mask (for protection against aerosols if necessary).
・Equipment to respond to emergencies (emergency crash cart).

Precautions for vaccination to persons who have specific background

① Persons required caution for vaccine inoculation

When health workers inoculate the following persons with LC16m8, carefully examine and determine the advisability of vaccination based on the person's health status and constitution.

Healthcare workers should inoculate with LC16m8 after providing a thorough explanation of the importance of preventive vaccination, side effects, usefulness, and obtaining consent reliably.

1) Persons with a history of hypersensitivity, such as shock and anaphylaxis (hives, respiratory distress, lip oedema, and laryngeal oedema), to foods and drugs containing gelatin.
2) Persons with underlying illnesses such as cardiovascular disease, kidney disease, liver disease, blood disease, and developmental disorders.
3) Persons who have experienced fever within 2 days of vaccination and those with symptoms suspected of an allergy, such as generalised exanthem.
4) Persons with a history of convulsions.
5) Persons with a prior diagnosis of immunodeficiency and those who have a close relative with congenital immunodeficiency.
6) Persons who might be allergic to a vaccine ingredient.
7) Persons with renal impairment.
8) Persons with liver functional impairment.
9) Women with reproductive potential.
   Health workers should inoculate women who use contraception for at least 1 month prior to vaccination with LC16m8 and advise them not to get pregnant for 2 months after vaccination.
10) Pregnant women
   Health workers should not inoculate women known to be pregnant with LC16m8.
11) Breastfeeding women
   Health workers should consider the benefits of inoculating breastfeeding women with LC16m8, the benefit of breastfeeding, and the continuation or discontinuation of breastfeeding.

② Important basic precautions

LC16m8 is to be used following the Japanese "Immunization Act" and the "main points for the implementation of routine vaccination."

1) Health workers should check the health status of the vaccine recipient before vaccination, including reviewing their medical history, checking body temperature, and conducting a medical examination (visual examination and

auscultation).

2) LC16m8 contains gelatin derived from a stock solution (≤ 0.15 w/v%). It has been reported that administering vaccines containing gelatin can cause hypersensitivity reactions, such as shock and anaphylaxis (hives, respiratory distress, lip oedema, and laryngeal oedema, among others). Therefore, healthcare workers should record and review the person's medical history thoroughly and observe carefully after vaccination.

3) LC16m8 contains streptomycin as an additive. Therefore, hypersensitivity may occur in persons with sensitivity to streptomycin. After vaccination, healthcare workers should carefully observe the recipient. If symptoms appear, healthcare workers should administer appropriate treatment.

4) Healthcare workers should inform the vaccine recipient and/or their guardian in advance to avoid exercising on the day of vaccination; they should also keep the vaccination site clean and monitor the recipient's condition after vaccination. If abnormal localised reactions or changes in their condition occur and abnormal symptoms appear, such as high fever, convulsions, and severe skin symptoms, the recipient and/or their guardian should consult healthcare workers immediately.

③ Interactions

1) Contraindicated concurrent use (do not use in combination)

Drug name	Clinical symptoms and treatment methods	Mechanism and risk factors
Adrenocorticosteroids such as prednisolone Immunosuppressants ・Cyclosporin (Sandimmun) ・Tacrolimus (Prograf) ・Azathioprine (Imuran)	Inoculation of LC16m8 can cause the appearance of symptoms resembling smallpox.	Persons receiving drugs with immunosuppressive effects, particularly long-term or high doses or within 6 months of discontinuation of taking these drugs, may have impaired immune function. These persons may enhance or sustain vaccine virus infection.

2) Drugs with concurrent use (caution with concurrent use)

Drug name	Clinical symptoms and treatment methods	Mechanism and risk factors
Other live vaccines (injectable) ・Measles vaccine ・Rubella vaccine ・Mumps vaccine ・Varicella vaccine ・BCG vaccine ・Yellow fever vaccine	Other live vaccines (except oral live vaccine) should usually be administered after at least 27 days.	Interference from other live vaccines (injectable) may prevent the multiplying virus in LC16m8, and immunity may not be acquired.

Precautions for vaccination dosage and administration

① Vaccination intervals with other live vaccines (injectable)

Healthcare workers should inoculate persons who took other live vaccines (injectable) with LC16m8 at least 27 days apart.

② Simultaneous vaccination

Healthcare workers can inoculate persons with LC16m8 at the same time as other vaccines if medical doctors deem it necessary.

Side effects

The following side effects may occur. Therefore, healthcare workers should carefully observe the vaccine recipients. If the abnormality is observed, healthcare workers should administer appropriate treatment.

① Serious side effects

1) Shock, anaphylaxis (both incidences unknown)

Shock and anaphylaxis (hives, respiratory distress, lip oedema, and laryngeal oedema) can occur.

2) Convulsions (< 0.1%)

Febrile convulsions can occur.

② Other side effects

	Incidence unknown
Hypersensitivity	Rash*, allergic dermatitis, erythema multiforme
Localised reaction (inoculation site)	Inoculation site reaction
Others	Fever*, swelling axillary lymph nodes*

* These can occur for approximately 10 days after inoculation.

③ Symptoms observed in clinical trials

Children (data at the time of vaccination of approximately 50,000 children between 1974 and 1975)

Approximately 50,000 cases of children, mainly one to seven years old, were inoculated with LC16m8 in the clinical trial. The following clinical symptoms have been reported regarding 10,578 cases that could be observed in detail. Swelling axillary lymph nodes in 12-19% of cases, fever (between 4–14 days after inoculation) in 7.7% of cases, febrile convulsions in 3 cases, eczema vaccinatum in 1 case, autoinoculation (blisters caused by virus inoculation from the inoculation site to another site caused by the hand) in 9 cases, vaccinia (blisters and abscesses observed near the inoculation area) in 28 cases, and vaccinal eruption (allergic eczema appearing in various forms such as hives and erythema observed from approximately day 7–10 after vaccination) in 8 cases. Electroencephalography (EEG) was performed 14 days after inoculation with LC16m8 in 56 cases, and none showed abnormalities on EEG.

Adults (data at the time of vaccination of approximately 268 adults from 2005 to 2010)

Lymph node oedema in 19.4% (52/268 cases), vaccination site erythema in 5.2% (14/268 cases), fever in 1.5% (4/268 cases), malaise in 0.7% (2/268 cases), post-vaccine complications (causing satellite lesions/rash other than in the vaccination site) in 0.7%, vaccination site swelling in 0.4 %, and post-vaccination autoinoculation (suspected ectopic inoculation) in 0.4%.

Adults (referring to data at the time of vaccination of 3,221 adults from 2002 to 2005, JAMA. 2009;301(10):1025-1033)

Among 3,221 cases, monitoring was performed in 1,066 cases, and adverse events were reported in 148 cases.

There was lymph node swelling in 96 cases, fever (> 37.5°C) in 21 cases, itching and hives in 7 cases, flu-like symptoms in 6 cases, headache in 5 cases, muscular pain of the neck, check, and upper limbs in 4 cases, cervical lymph node swelling in 3 cases, diarrhoea in 2 cases, acute neurosensory deafness in 1 case, dizziness in 1 case, peri-orbital swelling in 1 case, and joint pain in 1 case.

Important points when handling the vaccine

① Storage before dissolution

1) Cold storage:

(1) Vaccines can be stored for 2 years between 2℃ and 8°C.

(2) Once vaccines are transferred to cold storage, they must not be re-frozen. Vaccines must be used within the validity period and no later than 2 years after transfer to cold storage.

2) Room temperature storage:

(1) Vaccine can be stored for 4 weeks at room temperature (37℃ or below).

(2) Once vaccines are transferred to room-temperature storage, they must not be returned to frozen or cold storage. They must be used within the validity period and no later than 4 weeks after transfer to room-temperature storage.

② Storage after dissolution

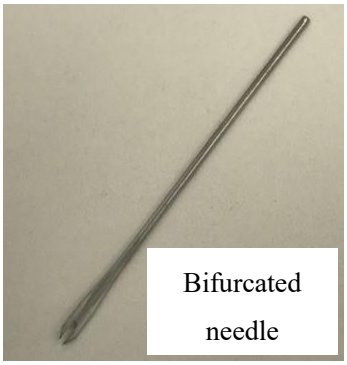
1) After dissolving with the provided diluent, use it within 24 hours if stored at room temperature (37°C or below). If stored under refrigeration (2–6°C), use it within 1 month.
2) LC16m8 does not contain a preservative. If dispensing and storing LC16m8 in small portions with sterilized polypropylene cryo-tubes after dissolution, appropriate aseptic handling should be required.
The vaccine solution in the vial removed the aluminium cap and rubber stopper in a non-sterile environment should be used immediately. The remaining vaccine should not be stored again and should not be used for the next vaccination. In this case, the remaining vaccine must be discarded.

③ Other important points

1) Do not store below -35°C as the rubber stopper may deteriorate or break.
2) The LC16m8 virus is sensitive to sunlight and is rapidly inactivated. Avoid exposing LC16m8 to light, both before and after dissolution.

B. At vaccination

Vaccination equipment



Bifurcated needle

For vaccination, a sterilized bifurcated needle is usually used.
The vaccination needle must be changed for each person to be inoculated.

The flow up to vaccination completion (※refer to the package insert as needed)

① Preparing vaccine

1) Do not mix LC16m8 with other vaccines.
2) Remove the plastic cap from the freeze-dried vaccine vial and the provided diluent vial (Do not remove the aluminium cap at this moment). Disinfect the rubber stopper and surrounding area with alcohol.
3) Draw 0.5 mL of the provided diluent using a syringe through the rubber stopper from the provided diluent vial and transfer it to the freeze-dried vaccine vial.
4) Dissolve well, and after confirming the contents, remove the aluminium cap (with split structure) and the rubber stopper.
5) If healthcare workers need to inoculate persons with LC16m8 in succession as a massive vaccination, 0.5ml of vaccine solution dissolved by 0.5ml of the provided diluent can generally be used for 250 or more persons from one vial using

a bifurcated smallpox vaccination needle. *Estimating a fluid volume of 1 ± 0.5 μL (design value) per bifurcated smallpox vaccination needle collection.

② Vaccination site preparation

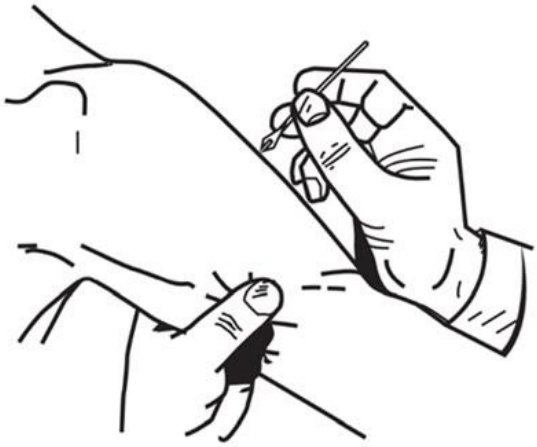
The vaccination site is the lateral upper arm at the origin of the triceps brachii muscle, which is disinfected with an alcohol swab that has been firmly wrung and left to dry (to avoid virus inactivation at the time of vaccination).

③ Vaccination

Soak the tip of the bifurcated needle (bifurcated side) in the vial or tube with the dissolved vaccine.

Check that the tip of the bifurcated needle holds the vaccine solution and inoculate with the vaccine using the multiple puncture technique.

1) The inoculator holds the bifurcated needle in the dominant hand and holds the arm from the back of the inoculation site with the other hand. The skin at the vaccination site can be slightly stretched at this time. (see image below)



2) The wrist of the hand holding the needle should rest on the skin of the vaccinated persons, with the needle held perpendicular to the skin.
3) The bifurcated needle is moved to press lightly on the skin, and the vaccine is inoculated to an area of approximately 5 mm (Slight bleeding may occur. Aim to press 15 times.
4) The vaccination area extends approximately 5 mm in diameter on the lateral upper arm at the origin of the triceps brachii muscle.
5) When using another bifurcated needle, the puncture should be made following the necessary precautions.
6) The residual vaccine solution in the vaccination site should be wiped away with a firmly wrung alcohol swab after 1 to 3 minutes.

Post-vaccination observation

After vaccination, the person receiving the vaccination must remain in an appointed area and be observed for at least 30 minutes.

Management of the vaccination site after returning home (guidance for persons receiving vaccination)

※ Refer to the separate document if needed

Healthcare workers should instruct persons inoculated with LC16m8 of the following:

- Avoid bathing, drinking alcohol, and heavy exercise on the day of receiving the vaccination and avoid touching the vaccination site until the next day.
- According to previous studies, over 90% of vaccine recipients' vaccination sites show any local inflammatory reaction such as erythema, swelling, induration, blisters, and scabs or crusting after the vaccination.

● In many cases, the vaccine site will become reddish and swelling 3-4 days after vaccination. After the vaccination site becomes reddish and swelling, blisters will appear at the vaccination site. The blisters at the vaccine site will be dried and become scabs. Do not pick at the scabs on purpose. The scabs will fall off naturally. After the scabs fall off, the vaccination site will typically become a scar after 2-3 weeks of the vaccination. After that, the vaccination site can be touched directly. ● Avoid touching blisters and scabs directly at the vaccination site; apply gauze as needed ● If the person receiving the vaccine or someone else touches the vaccine site directly with their fingers, they should thoroughly wash their hands. ● Pay attention to avoid other persons touching the vaccine site. ● Avoid becoming pregnant for 2 months after vaccination. ● Be aware of not being able to donate blood for 2 months after vaccination.
Other precautions
Horizontal transmission from a vaccinated person to a non-vaccinated person has been reported with the use of a different live vaccine strain (injectable drug). Avoid directly touching the vaccination site; wash hands thoroughly if the site is touched.

C. Confirmation of 'take'

What is 'take'?
'Take' has been used as a surrogate indicator of immunogenicity, a condition in which any local inflammatory reaction occurred, such as erythema, swelling, induration, blisters, and crusting at the inoculation site on days 10–14 (broad definition).
Confirmation method
To confirm 'take', a physical examination will be performed between 10 and 14 days after inoculation.

References

- Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 "KMB" package insert revised July 2024, Ver2.0 written in Japanese
- WHO Mpox (monkeypox) treatment (https://www.who.int/health-topics/monkeypox/#tab=tab_3 accessed on August 12, 2024)
- WHO Vaccines and immunization for monkeypox: Interim guidance published November 16, 2022 (https://www.who.int/publications/i/item/WHO-MPX-Immunization accessed on August 12, 2024)
- Eriko M, Mugen U et al. Mpox Neutralizing Antibody Response to LC16m8 Vaccine in Healthy Adults, NEJM Evid 2024;3(3) DOI: 10.1056/EVIDoa2300290
- Smallpox and mpox (orthopoxviruses): WHO position paper, August 2024 WER: No 27, 2024, 99, 351–362 (https://iris.who.int/bitstream/handle/10665/378522/WER9934-eng-fre.pdf?sequence=1 accessed August 28, 2024)
- Report on the Deliberation Results by Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau published August 1, 2022 (https://www.pmda.go.jp/files/000247943.pdf accessed on August 28, 2024)
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- Risk Management Plan regarding Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 “KMB” for vaccine receipts and their families revised May 2023 written in Japanese (https://www.pmda.go.jp/RMP/www/261976/7cd35b30-7f15-4f82-a83c-9ab98e951cfe/261976_631340KD1037_02_001RMPm.pdf accessed August 31, 2024)
- Risk Management Plan regarding Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 “KMB” for health workers revised May 2023 written in Japanese (https://www.pmda.go.jp/RMP/www/261976/7cd35b30-7f15-4f82-a83c-9ab98e951cfe/261976_631340KD1037_01_001RMPm.pdf accessed August 31, 2024)

To persons receiving the smallpox vaccine,

We would like to inform you about some important issues regarding the smallpox vaccination.
Please read and make sure you understand the following.

I. Smallpox vaccine

The smallpox vaccine is a live vaccine of the same vaccinia virus strain as that used for Mpox (monkeypox). It has been reported that the smallpox vaccine is 85% effective in preventing Mpox infection before exposure to the Mpox virus. The World Health Organization (WHO) also recommends that persons at risk of exposure to Mpox receive this vaccine as a preventive vaccination. On 2 August 2022, a freeze-dried smallpox vaccine prepared in cell culture LC16 “KMB” was approved for an additional indication of prevention against Mpox in Japan.

II. Persons who are unsuited to receive preventive vaccination

The following persons cannot receive the smallpox vaccine:

1. Persons who have had anaphylaxis caused by an ingredient of this vaccine.
2. Persons presenting high fever.
3. Persons who have suffered a severe acute illness.
4. Persons with illness presenting with clear abnormality in immune function and those receiving treatment that can cause immunosuppression.
   *If taking immunosuppressive medications, please inform health workers before vaccination.
   *Persons who are HIV positive should inform healthcare workers to check their CD4 count before vaccination.
5. Persons who are pregnant or who might be pregnant.
6. Persons with contagious skin disease and those who might get worse because of the preventive vaccine.
7. In addition to the persons listed above, persons are not under suitable conditions to receive preventive vaccination.

Women who are presently breastfeeding should inform healthcare workers before vaccination.
For more details, please consult healthcare workers.

III. Vaccination method

The vaccine is to be inoculated using a special needle for the smallpox vaccine and pressed lightly 15 times on the skin. Slight bleeding can occur. Before vaccination, the site will be disinfected using an alcohol cotton swab and be inoculated with the vaccine once the site has fully dried (to prevent vaccine inactivation).
After vaccination, the residual vaccine solution at the vaccination site will be wiped away with a firmly wrapped alcohol swab after 1–3 minutes (to prevent autoinoculation; please refer to details of these side effects below in detail).
The vaccination site does not need to be covered with gauze. However, if blisters and scabs appear, please cover them with gauze and avoid touching them.

IV. Precautions after vaccination

Persons who took the smallpox vaccine should follow these instructions:

- Avoid bathing, drinking alcohol, exercising heavily on the day of vaccination, and avoiding touching the vaccination site until the next day.
- In many cases, the vaccine site will become reddish and swelling 3-4 days after vaccination.
  After the vaccination site becomes reddish and swelling, blisters will appear at the vaccination site.
  The blisters at the vaccine site will be dried and become scabs. Do not pick at the scabs on purpose. The scabs will fall off naturally.
  After the scabs fall off, the vaccine site will become scarred after 2-3 weeks of vaccination, and then you will be able to touch the site directly
- Avoid touching blisters and scabs directly at the vaccine site and apply gauze as needed.
- If you or someone else touches the vaccination site directly with you/their fingers, please thoroughly wash your hands.
- Pay attention to avoid other persons touching the vaccination site.
- Avoid becoming pregnant for 2 months after vaccination.
- Note that you will not be able to donate blood for 2 months after vaccination.
- Healthcare workers will check the vaccine state 10–14 days after vaccination to ensure the appearance of immunisation signs.

V. Side effects

Although serious side effects of the smallpox vaccine are rare, the following can occur:

Serious side effects

Shock and anaphylaxis (both incidences unknown) and febrile convulsions (< 0.1%).

Other side effects

Inflammatory reactions at the vaccine site and general reactions might appear up to 10 days after vaccination, including fever, swelling of axillary lymph nodes, malaise, itchiness, hives, headache, muscle-pain-like pain, autoinoculation (blisters caused not only at the vaccination site but also on another part of the body due to vaccine virus inoculation occurring through the hands), vaccinola (the appearance of blisters and abscess around the vaccination site), and vaccinated eczema (allergic eczema appearing in a hive or erythema-like form seen approximately 7–10 days after vaccination).

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VI. Precautions following vaccination

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- Avoid touching blisters and scabs directly at the vaccine site and apply gauze as needed.
- If you or someone else touches the vaccination site directly with you/their fingers, please thoroughly wash your hands.
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