



SOP Preparation and administration of the intradermal and subcutaneous vaccination against monkeypox/mpox with Jynneos® mpox Vaccine

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This SOP describes the handling, preparation and administration of the mpox vaccine Jynneos®. The vaccine is usually administered subcutaneously. If the vaccine is in short supply, it will be administered to most people intradermally in order to obtain more doses. Subcutaneous administration during a vaccine shortage is recommended only for certain groups of people (see the recommendations issued by the Federal Commission for Vaccination (FCV)): [Analytical framework and recommendations on vaccination against monkeypox](#) [in German] Vaccine MVA-BN® (Modified Vaccinia Ankara from Bavarian Nordic) (as at 01.09.2022)

1. General information on Jynneos®

| | |
|----------------------|---|
| Description | A pack of Jynneos® contains 20 vials. A type I glass vial with stopper (bromobutyl rubber) contains 0.5 ml of suspension |
| Vaccination schedule | The vaccination schedule for Jynneos® consists of two doses at least 4 weeks apart. |
| Administration | Subcutaneous or intradermal (see explanatory notes below) |
| Dosage | Subcutaneous injection: 0.5 ml (whole vial) Intradermal injection: 0.1 ml (a fifth of the vial) |

2. Administration and dosage

The standard administration route for Jynneos® is subcutaneous injection (s.c.). However, a [clinical trial](#) with around 500 adults showed that two intradermal injections of 0.1 ml generated antibody titres that were comparable with those produced by two subcutaneous 0.5 ml doses. Administration of the doses 4 weeks apart is recommended for both administration routes.

In order to ensure that the target group is vaccinated promptly during a vaccine shortage, 2 x 0.1 ml of Jynneos® will be administered intradermally (i.d.) during the mpox vaccination campaign (while supplies of the vaccine are limited). For this purpose, we recommend using the same kind of insulin syringes at all times in order to avoid incorrect dosages. The insulin syringe should contain a volume of 1 ml/50 I.U. The intradermal injection must be administered by a trained professional. The intradermal administration technique must be taught and practised sufficiently, e.g. with NaCl, before a professional can be considered as "trained".



3. Storage and handling of Jynneos®

The shelf life of Jynneos® when stored in the frozen state is as follows:

- 3 years at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$. Shelf-life after thawing: 8 weeks at 2°C to 8°C .
- 5 years at $-50^{\circ}\text{C} \pm 10^{\circ}\text{C}$. Shelf-life after thawing: 24 weeks at 2°C to 8°C .
- 9 years at $-80^{\circ}\text{C} \pm 10^{\circ}\text{C}$. Shelf-life after thawing: 8 weeks at 2°C to 8°C .

The shelf life and storage duration of MVA-BN vaccine (JYNNEOS, IMVANEX) when stored at -50°C or -80°C is maintained even if the vaccine is stored (or transported) at -20°C at any time within the respective shelf life, as long as the cumulative duration at -20°C is less than 3months.

The vaccine should be used within the printed expiration date on the pack. Please note that the expiration date is not printed on individual vials.

| Refrigerator: <i>Between 2°C and 8°C</i> | At room temperature: <i>Between 8°C and 25°C</i> |
|---|---|
| Unpunctured vials can be stored in the refrigerator for up to 8 weeks . Punctured vials can be stored at refrigerator temperature for up to 8 hours . <i>Once the vial is punctured, the shelf life is noted (remaining 8 hr.).</i> | Unpunctured vials can be stored at room temperature for up to 6 hours . <i>As soon as the vaccine is taken out of the refrigerator, the shelf life must be noted on the vial (remaining 6 hr.).</i> |

Frozen Jynneos® vaccine takes about 10 minutes to thaw. Do not refreeze the vaccine once it has been thawed. The vaccine should not be administered directly from the refrigerator. Leave the vials at room temperature for 3 to 5 min. before drawing up the vaccine.

Do not draw up the individual vaccine doses in advance, but administer them directly after they have been withdrawn. Reason: No data are available on the vaccine stability of prepared syringes (either when stored in the refrigerator or at room temperature).

4. Checking the indication and briefing

- Check the indication and rule out contraindications according to the latest FCV recommendations (e.g. informed consent form, incl. explaining about off-label vaccine and arranging for the form to be signed).
- Information about administration-specific side effects:
 - i.d. administration: Possible local skin reactions, including redness, discolouration and induration, which can persist more than 6 months after injection.
 - s.c. administration: Burning sensation during the injection.
- Information about frequently occurring systemic side effects (headache, muscle pain, fatigue, nausea, fever, chills).



5. Preparation of the Jynneos® vaccine from 1 vial

| i.d. administration: 5 doses | s.c. administration: 1 dose |
|---|--|
| Use aseptic technique and hand hygiene before preparing the vaccine | |
| Material preparation per vial: <ul style="list-style-type: none"> • 5 insulin syringes (1 ml, U-100 / 50 I.U. with integrated needle 0.3 mm x 12 mm) • 1 antiseptic swab | Material preparation per vial: <ul style="list-style-type: none"> • 1 syringe without dead volume (1 ml) • 1 antiseptic swab • 1 withdrawal cannula (0.6 mm x 30 mm) • 1 subcutaneous cannula (0.5 mm x 16 mm) |
| Check the expiry date and time of the vial. | |
| Hold the vial upright and swirl the vaccine carefully for 30 seconds. Check the suspension at this time: suspension should be milky-light yellow to pale white. Discard the vaccine if the vial is damaged, the suspension contains foreign particles or if its physical appearance is unusual. | |
| Remove the protective cap and disinfect the vial stopper (N.B.: rubber stopper must be completely dry before insertion). | |
| Withdraw five doses of 0.1 ml. Check the insulin syringe to ensure that 10 I.U. have been drawn up. No air bubbles should be present. N.B.: Use a different puncture site for each withdrawal in order to avoid damaging the rubber and to maintain asepsis (e.g. clockwise). | Draw up all the vial contents (syringe marking at 0.5 ml/50 I.U.). No air bubbles should be present. |
| Put the cap back on the cannula (caution!) | Needle change for s.c. injection (0.5 mm x 16 mm) |
| Mixing residual vaccines from several vials is <u>not</u> permitted. Administer the vaccine dose directly. | |

Important: Do not leave prepared syringes lying around for long periods, but administer vaccine immediately (within 30 min). No data are available on the vaccine stability of prepared syringes (either when stored in the refrigerator or at room temperature).

Disposal

Unused vaccine and waste materials are discarded as medical waste.

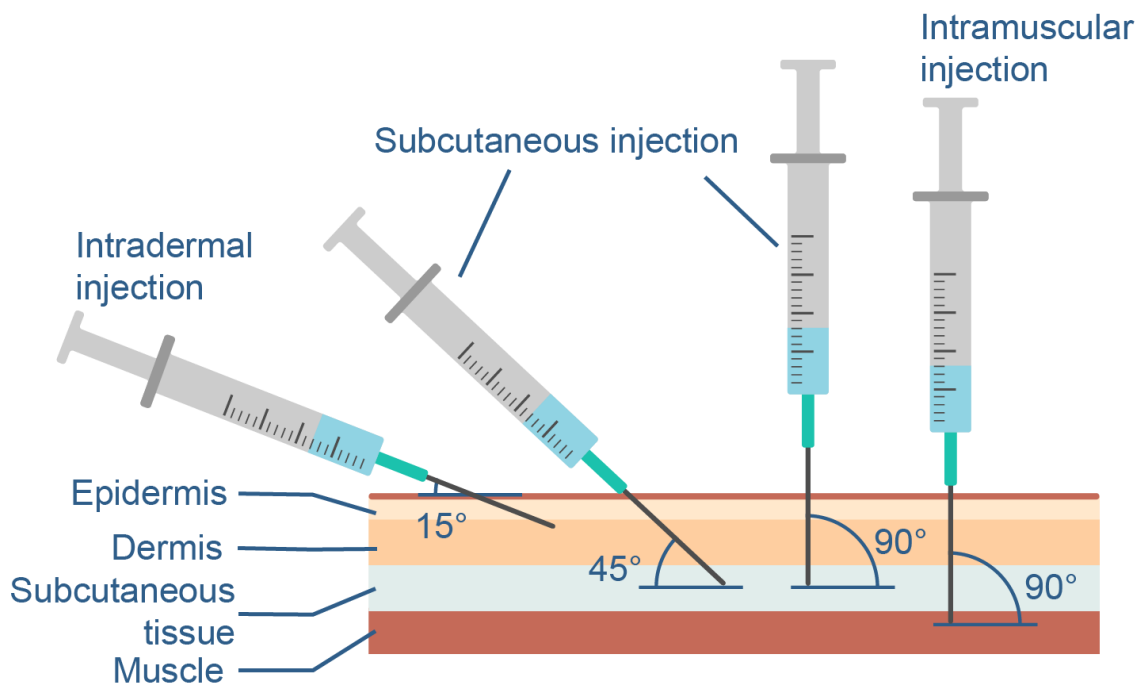


6. Preparing the vaccination

Material & hygiene measures

| i.d. administration: 5 doses | s.c. administration: 1 dose |
|---|--|
| <ul style="list-style-type: none">• Jynneos® vaccine drawn up in insulin syringe (check: 0.1 ml)• Antiseptic pads• Swab• Plaster | <ul style="list-style-type: none">• Jynneos® vaccine drawn up in 1 ml syringe with s.c. cannula up to 16 mm (check: 0.5 ml)• Antiseptic pads• Swab• Plaster |
| <ul style="list-style-type: none">• Hand disinfection• Gloves | |

Subcutaneous and intradermal administration of the vaccine





7. Intradermal (i.d.) administration of the vaccine

Administration site One hand's width (5-10 cm) below the elbow on the inside of the forearm (palmar aspect).

Preparation Disinfect the injection site (wait until the site is completely dry).

Injection

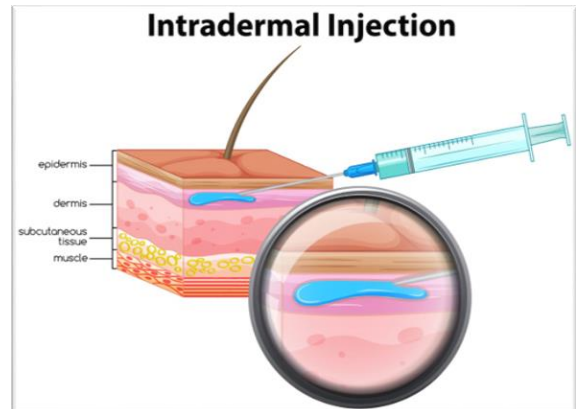
- Pull skin taught
- Puncture the skin at an angle of 5-10 degrees (holding the syringe almost flat against the skin in order to remain in the upper skin layer (dermis))
- Carefully advance the needle a few mm into the dermis with the bevel of the cannula face up.

Tip: The needle should be visible under the skin.

- Inject the vaccine slowly.
- If the procedure is carried out correctly, clearly discernible resistance can be felt during the injection.

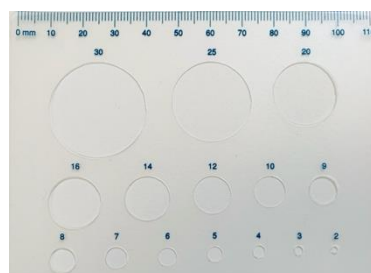
Important: A visible wheal must be formed in order to guarantee intradermal injection (6-8 mm in diameter).

- Wait briefly before removing the needle, then withdraw the cannula.
- Dispose of the syringe / needle directly in the sharps box.
- Tell the subject that the site should not be touched, scratched or washed for the next 3-4 hours.
- At the subject's request, a plaster can be applied carefully, without manipulating the wheal, over the injection site.



Check

If a wheal with a diameter of 6 - 8 mm fails to appear or if its contents leak out, it must be assumed that the vaccine has not been injected into the dermis. In this case, a second dose is administered intradermally.



For quality assurance purposes we recommend the use of templates to measure the size of the wheal. The relevant template should be placed carefully over the wheal in order to prevent it from leaking as a result of the application of pressure. The template should be disinfected after each use.

Video: [How to administer a JYNNEOS vaccine intradermally](#)



8. Subcutaneous (s.c.) administration of the vaccine

Administration site Back of the upper arm (dorsal aspect):



Preparation Disinfect the injection site (wait until the site is completely dry).

Injection

- Skin fold technique: Lift a thick fold of skin at the injection site with thumb and index finger.
- At an injection angle of 45 degrees, quickly insert the injection cannula a few millimetres deep.



Obese people: Administer at an injection angle of 90 degrees without a skin fold.



- Inject the vaccine slowly.
- On completion of the injection, leave the cannula in the subcutaneous fatty tissue for 3–5 seconds in order to avoid any backflow of the active substance.
- Remove the injection cannula quickly.
- Slightly compress the injection site if needed with the swab and apply a plaster.
- Dispose of the syringe directly in the sharps box.



9. Documentation

Details for the i.d. administration: Name, date of birth, date of vaccination, vaccine and administration quantity (Jynneos® 0.1 ml), administration route (i.d.), lot no., informed consent for off-label use

Details for the s.c. administration: Name, date of birth, date of vaccination, vaccine and administration quantity (Jynneos® 0.5 ml), administration route (s.c.), lot no., informed consent for off-label use

Healthcare professionals are required to report any observed adverse drug reactions (ADRs), including adverse vaccine reactions (AVRs), [to Swissmedic](#). This applies to serious or previously unknown reactions, which are subject to a statutory reporting obligation according to Art. 59 Therapeutic Products Act



Sources

Literature sources

FOPH: <https://www.bag.admin.ch/en/mpox-monkeypox>

CDC: <https://www.cdc.gov/poxvirus/monkeypox/files/interim-considerations/guidance-jynneos-prep-admin-alt-dosing.pdf>

EMA: https://www.ema.europa.eu/en/documents/other/considerations-posology-use-vaccine-jynneos/imvanex-mva-bn-against-monkeypox_en.pdf

Study comparing subcutaneous versus intradermal administration of MVA vaccine
<https://www.sciencedirect.com/science/article/pii/S0264410X15008762>

Image sources

<https://idevax.com/intradermal-injection/>

<https://www.istockphoto.com/de/grafiken/intramuscular-injection>

Video source

Center for Disease Control and Prevention (CDC): Video on how to administer a JYNNEOS vaccine intradermally: <https://www.youtube.com/watch?v=zWZ4VaF3IdA>