

COVID-19 Vaccination Program Procedures

Management of Moderna elasomeran (SPIKEVAX) 0.1mg/mL COVID-19 vaccine from refrigerator to administration

Formulation registered for children at 6 months to < 6 years of age



Last updated: 1 September 2022

Responsibility

Staff preparing Moderna elasomeran (SPIKEVAX) COVID-19 vaccine 0.1mg/mL for 6 months to <6 years of age formulation for administration must follow this procedure. When working in pairs, it is the responsibility of both people to continue to follow this procedure and observe all local COVID-19 precautions, including maintaining social distancing where possible.

Overview

Moderna elasomeran (SPIKEVAX) COVID-19 vaccine 0.1mg/mL for 6 months to <6 years of age formulation must be thawed before use following removal from a frozen storage environment. Refer to 'Management of Moderna elasomeran (SPIKEVAX™) 0.1mg/mL COVID-19 vaccine from a standard temperature (-20°C) freezers to refrigerator – Formulation registered for children at 6 months to <6 years of age' for information on this procedure.

A thawed unpunctured vial can be stored at 2°C to 8°C for 30 days and 24 hours at 8°C to 25°C.

Vials



- Vials are 50mm x 24 mm with a blue top.
- Weight is 15.8 g. Volume is 2.5 ml
- The concentration of each vial is 0.1 mg/ml
- Each vial contains 10 doses of 0.25ml
- The vial DOES NOT require a diluent to be added
- Allow the thawed vial to sit at room temperature for 15 mins before administration, if the thawed vial has been stored at 2°C - 8 °C prior to removal from refrigerator

Cartons



- Single carton holds 10 multidose vials
- Dimensions are 53mm x 60mm x 137mm (WxHxL)
- Weight is 206g

Procedure

1. Removal of thawed vaccines from the refrigerator

1. Check the temperature display and ensure that the refrigerator has not deviated from between +2°C and +8°C. If a deviation has been observed, DO NOT USE the multi-dose vial, quarantine the vials, advise your senior executive and contact the Australian Government Vaccine Operations Centre (VOC) on 1800 318 208 using the NSW Health COVID-19 vaccine cold chain breaches reporting form. Refer to [NSW Health policy directive PD2020_028 Vaccine Storage and Cold Chain Management](#).
2. Perform hand hygiene with either soap and water or an alcohol-based hand rub (ABHR) before gathering supplies or handling vials.
3. Remove only the required number of thawed vaccine vials from the refrigerator. If there is more than one vial tray, use the vials with the shortest expiry. One vial contains sufficient vaccine for ten doses.
4. To reduce waste, the number of vials removed should be enough to cover no more than approximately 1 hour of anticipated usage when stored at room temperature. Note: the thawed **unpunctured** vials of Moderna elasomeran (SPIKEVAX) COVID-19 vaccine 0.1mg/mL for 6 months to <6 years of age formulation can be stored at room temperature (between 8°C and 25°C) for up to 24 hours.
5. Seal the vaccine vials that have been removed from the fridge into a zip lock bag.
6. Each vial removed from the refrigerator should have an expiry date and time applied by completing a 'Room Temperature Expiry Label' via an electronic process e.g. iPharmacy. Include:
 - Date and time vaccine vial was removed from the refrigerator (Use 24-hour clock format).
 - Date and time of expiry. The expiry is 24 hours from the point the vaccine vials are removed from the refrigerator and kept at room temperature (between 8°C and 25°C).
 - Batch number of the vaccine vials.
 - Signature of person completing the label (electronic system, e.g. iPharmacy is permitted e.g. configured from Username and Password).
7. Attach the label to the zip lock bag containing the vaccine vial (one per zip lock bag).
8. Obtain a check (of the time removed from fridge, calculated expiry and batch number) from a second person. The second person must document this check by signing the label by electronic means.
9. Take the bag to the vaccine preparation station and place it in an empty lidded box labelled 'VACCINE VIALS'. Confirm this box is empty before adding the new bag of vials. Close the lid on the box. If using a monitored cold storage bag at 2 to 8°C, vaccine cold chain management must comply with the National Vaccine Storage Guidelines Strive for Five and NSW Health policy directive [PD2020_028 Vaccine Storage and Cold Chain Management](#).

2. Workstation preparation

1. The workstation must be clean and clear of any other materials or objects, other than what is necessary for the preparation and drawing up of the vaccine. Ensure that there are no previously drawn up vials remaining in the workspace.
2. Clean the workstation with a neutral detergent wipe and discard into a general waste bin.
3. Perform hand hygiene with either soap and water or an alcohol-based hand rub (ABHR).
4. Ensure a yellow sharps container with enough free capacity is available.
5. Ensure a permanent black pen is available.
6. Perform hand hygiene.
7. Put on an apron and any additional PPE including face mask and gloves.

3. Drawing up Procedure

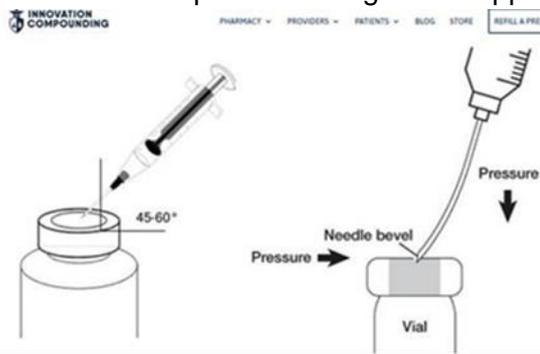
1. Remove a single vial of Moderna elasomeran (SPIKEVAX) COVID-19 vaccine 0.1mg/mL for 6 months to <6 years of age formulation from within the lidded box labelled 'VACCINE VIALS'. Close the lid of the box. If using a monitored cold storage box, check the temperature prior to removing a vial, and ensure that the temperature is within range.
2. Inspect the vial to ensure it has thawed and is within expiry with its integrity maintained. Note the thawing process in a refrigerator (2°C to 8°C) takes 2 hours and 30 minutes or 1 hour at room temperature (15°C to 25°C).
3. Allow the thawed vial to sit at room temperature for 15 mins before administration if the thawed vial has been stored at 2°C to 8 °C before being removed from refrigerator.
4. The vaccine contains no antimicrobial preservative, therefore ATAGI recommends that **punctured** vials (i.e. after the first dose has been withdrawn) should preferably be held between 2°C and 8°C, and cumulative storage of opened vials at 2°C to 25°C should not exceed 6 hours. Note: The vial does not contain antimicrobial preservatives therefore 6 hours storage of the punctured vial is recommended unless the vials are prepared using a method that minimises risk of microbial contamination. If the following conditions are met the punctured vial can be managed in accordance with the [TGA PI](#) and can be used for up to 19 hours at 2°C to 25°C after initial puncture (within the allowed use period of 30 days at 2°C to 8°C and 24 hours at 8°C to 25°C). The vial must be prepared:
 - by dedicated trained operators preparing vaccines aseptically
 - in an appropriate clean environment with minimal air movement
 - under the oversight of a pharmacist with experience in aseptic preparation
 - the vaccine is protected from light, returned to the refrigerator and stored at +2°C to +8°C when not in use to further minimise antimicrobial growth.
5. Prior to use, the thawed vaccine should be white to off white in colour and may contain white or translucent product-related particulates. If particulates or discolouration appears to be present, verify with a second person and quarantine/retain this vial and notify your pharmacist or team leader. Do not use this vial for administration.
6. Do not shake. Swirl the vial a few times gently after thawing and before each withdrawal.
7. Remove the protective plastic cap from the top of the vial and inspect the bung to ensure integrity.

8. Cleanse the vaccine vial stopper ('scrub the hub' and allow to dry) with a single use 70% alcohol swab and discard the swab into a general waste bin.

The procedure used to draw up the vaccine will be dependent on the preferred drawing up method that has been agreed on for consistent use at the hub/clinic i.e. multiple puncture or single puncture technique. This technique should subsequently be consistently used by all individuals involved in the drawing up process in that hub/clinic.

3.A Multiple puncture Technique

10. Swirl the vial gently a few times before each withdrawal.
11. The needle should be inserted at a 45–60° angle with the opening of the needle tip facing up (i.e., away from the stopper). A small amount of pressure is applied, and the angle is gradually increased as the needle enters the vial. The needle should be at a 90° angle just as the needle bevel passes through the stopper.



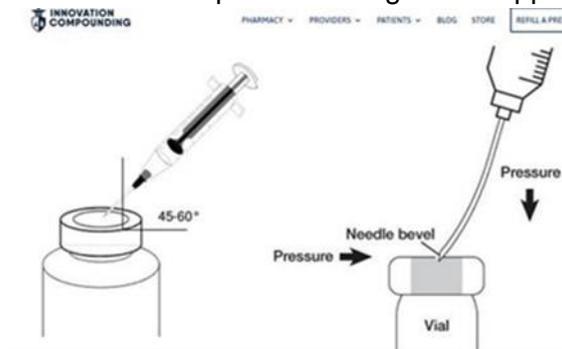
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12. Use a new, sterile 25G 25mm length needle and 1 mL syringe (Luer Lock, Leur Slip or fixed needle) to draw up each new 0.25 mL dose by re-puncturing the bung.
13. Ensure each re-puncture occurs at a different site on the bung.
14. Recap the clean needle using either a single-handed technique, forceps, or a suitable protective guard designed for re-sheathing. The needle must be properly recapped, and the sheath must not be held in the fingers.
15. If the dose is not being administered immediately document the vial batch number, vial expiry, prepared syringe expiry (i.e. six hours after first dose removed from vial date and time) and sign. This may be documented using a Syringe Label via an electronic system, e.g. iPharmacy. Obtain a check (of vial batch, vial expiry, calculated prepared syringe expiry) from a second authorised worker. The second authorised worker must document this check by signing the label via an electronic means.
16. The dose is ready to administer the vaccine using the affixed needle that was used to draw up the dose. Do not affix a new needle for administration as this will result in partial loss of the drawn-up dose due to the dead space in the new needle.
17. The drawn-up vaccine should be administered as close to the time of preparation as possible and within the labelled expiry date/time. ATAGI recommends that when possible, pre-drawn doses in syringes should be used within 1 hour if kept at 2-25°C, and within 6 hours if kept at 2-8°C. This is to minimise any risk of microbial contamination. The 6 hours in the pre-drawn syringe must be within the 19 hours (if conditions of 3.4 are met) following the first access of the vial.

18. Repeat until all 10 doses are drawn up. Do not puncture the vial stopper more than 10 times.
19. Place vaccine vial in the tray with the 10 completed syringes.
20. If drawing up all doses at once the vial stopper does not need to be cleaned between drawing up each dose if aseptic technique is used and maintained. If all doses are not being drawn up at the same time the vial should be returned to the fridge as soon as possible and the vial stopper should be cleansed with a single use 70% alcohol swab prior to each access. Initial access time should be documented using a vial label via an electronic system, e.g. iPharmacy.
21. Do not remove another vial of vaccine from the lidded box until the vial has left the preparation workspace or has been discarded.
22. The pre-drawn syringes should be returned to a fridge (+2°C to +8°C) and protected from light if they are not for immediate administration

3.B Single puncture Technique

23. Swirl the vial gently a few times before each withdrawal.
24. The needle should be inserted at a 45–60° angle with the opening of the needle tip facing up (i.e., away from the stopper). A small amount of pressure is applied, and the angle is gradually increased as the needle enters the vial. The needle should be at a 90° angle just as the needle bevel passes through the stopper.



[Innovation Compounding - Proper Aseptic Technique to Prevent Coring of Sterile Vials](#)

25. Use a 1mL syringe (Luer Lock or Leur Slip) and 21G or 22G needle to withdraw 0.25mL.
26. Using forceps, remove the syringe, leaving the needle in the vial.
27. Attach a new, sterile 25G 25mm length needle.
28. Using forceps to steady the vial, attach a new 1mL syringe and withdraw another 0.25mL.
29. Repeat these steps to draw up all doses.
30. Document the vial batch number, this may be documented using a Syringe Label via an electronic system, e.g. iPharmacy. Include vial expiry, prepared syringe expiry and sign. Noting that ATAGI recommends that when possible, pre-drawn doses in syringes should be used within 1 hour if kept at 2-25°C, and within 6 hours if kept at 2-8°C. This is to minimise

any risk of infection. The 6 hours in the pre-drawn syringe must be within the 19 hours (if conditions of 3.4 are met) following the first access of the vial.

31. Place vaccine vial (needle removed) in the tray with the 10 completed syringes.
32. Obtain a check (of vial batch, vial expiry, calculated prepared syringe expiry and volume of vaccine) from an authorised health care practitioner. The authorised health care practitioner must document this check by signing the label or an electronic means.
33. The pre-drawn syringes should be returned to a fridge (+2°C to +8°C) and protected from light if they are not for immediate administration.
34. If using forceps, single use forceps must be discarded into the sharps container after each 2 hour drawing up session. If re-useable forceps are used these must be cleaned using a 70% alcohol swab after each 2 hour drawing up session.

4. Handover of prepared vaccine syringes to immuniser/administrator

Where vaccines are prepared and administered by different staff the handover process must be clearly documented as per local guidelines.

5. Administration of vaccine

1. Assemble the following materials required to administer prepared syringes:
 - i. Prepared syringe (needle attached) of 0.25 mL Moderna elasomeran (SPIKEVAX) COVID-19 vaccine 0.1mg/mL for 6 months to <6 years of age formulation x 1
 - ii. Kidney dish for prepared syringes
 - iii. Cotton wool
 - iv. Band-Aid
 - v. Sharps container.
2. Check the prepared vaccine syringe is within the expiry date and time. If the prepared syringe is past the expiry time DO NOT USE and notify the pharmacist and/or team leader.
3. Administration of prepared vaccines should be in accordance with local policy and the Australian Immunisation Handbook.
4. Sit patient and carer(s) in vaccination area, ensuring privacy if required.
5. Perform patient identification and pre-vaccination screening and assessment.
6. Administer vaccine intramuscularly. The recommended site of administration for individuals aged ≥ 12 months is the deltoid muscle of the upper arm. The vastus lateralis muscle in the anterolateral thigh is the recommended site for intramuscular vaccination in infants <12 months of age. The ventrogluteal area is an alternative site for intramuscular vaccination of infants <12 months of age. However, immunisation providers who choose to use the ventrogluteal area must be familiar with the landmarks used to identify the correct site. Further information is available on the Australian Immunisation Handbook website at <https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/administration-of-vaccines#route-of-administration>
7. Immediately discard used syringe and needle into sharps container (do not re-sheath the needle).
8. Provide patient and carer(s) with relevant post vaccination advice.

9. Ensure patient remains in the center for observation for at least 15 minutes post vaccination (or 30 minutes for people with a history of anaphylaxis or who carry an adrenaline autoinjector (e.g. EpiPen).

6. Additional advice

1. For additional clinical advice including advice on interrupted doses and diluent leakage when reconstituting, see [COVID-19 vaccine – Clinical considerations](#).