

AstraZeneca COVID-19 Vaccine Multidose Vial Preparation

9 April 2021

OFFICIAL

Purpose:

This document explains the process of preparing dose syringes from the COVID-19 AstraZeneca multi-dose vials (MDV). This includes the presentation of the vaccine, preparing your workstation, gathering equipment and step-by-step directions accompanied by photographs.

The latest ATAGI (Australian Technical Advisory Group for Immunisations) information for health care providers on [drawing up the AstraZeneca vaccine](#) and the suitability of AstraZeneca vaccine in people with history of clotting conditions have been included.

Important Information:

- AstraZeneca COVID-19 Vaccine (ChAdOx1-S) solution for injection is available in two presentations:
 - 8 doses of 0.5mL in a 4mL multi-dose vial (imported), or
 - 10 doses of 0.5mL in a 5mL multi-dose vial (Example 1)
- ATAGI strongly recommends using a 19-21-gauge bevelled needle for drawing up
- Administered as intramuscular injection via a 23-gauge (or 25-gauge) x 25mm needle (or 38mm needle for obese patients).
- AstraZeneca COVID-19 Vaccine does not require reconstitution or dilution.
- **DO NOT SHAKE. Protect from light. Refrigerate.**
- The vaccine does not contain any preservative. After first opening, use the vial within:
 - 6 hours when stored at room temperature (up to 30°C), **OR**
 - 48 hours when stored in a refrigerator (2°C to 8°C)

Vaccine Presentation:

- Each vial contains at least the number of doses stated.
- After withdrawing 8 or 10 full 0.5mL doses from the vial (depending on vial size), it may be possible to withdraw an additional full dose if low dead space needles and syringes are being used.
- Care should be taken to ensure a full 0.5 mL dose will be administered to the patient from the same vial. Where a full 0.5 mL dose cannot be extracted, the remaining contents must be discarded.
- Do not pool excess vaccine from multiple vials.
- The vial can be re-refrigerated, but after first opening the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours. After this time, the vial must be discarded.
- Vaccine drawn into prepared dose syringe should be used as soon as practical. There is data supporting stability of vaccine doses after withdrawal into a syringe for up to 6 hours at room temperature (as

reflected in the AstraZeneca COVID-19 vaccine [product information](#)). However, ATAGI recommends that, as much as possible, pre-drawn doses be used within an hour to minimise any remote potential risk of infection.

Equipment and Environment:

Confirm the preparation workstation is clear and free from any other vials of vaccine.

Clean workstation surface with a disinfectant wipe and discard into a clinical waste bin.

General equipment recommended (refer also specific consumables per vial below):

- Approved sharps bin with enough free capacity
- Clinical waste bin with enough free capacity
- Secure Pharmaceutical Waste Bin (1 per site) with enough free capacity
- Face mask – disposable (level 2)
- Minimum 60% alcohol-based hand rub
- Hospital grade disinfecting wipes or Isopropyl wipes for cleaning workstations and spills
- Labels: 'AstraZeneca COVID-19 vaccine stock removed from fridge label' (Example 2)
- Labels: 'AstraZeneca COVID-19 vaccine stock returned to fridge label' (Example 5)
- Labels: 'Quarantine' (Example 6)
- Opaque-lidded scheduling containers for storing vials removed from fridge.
- Digital clock
- Lamps and globes
- Tweezers, forceps, or a suitable protective guard designed for re-sheathing needles
- Indelible pens
- Thumb loop aprons (recommended)
- Gloves (optional)
- Goggles (optional)
- Refrigerated storage with temperature monitoring (every 5 minutes) and active alerts.

Vaccine Stock Management:

The appropriately authorised staff member (such as the Vaccine Inventory Coordinator) is to remove the required vial/s from refrigerated storage. Where there is more than one manufacturer's batch present, select stock with the closest expiry.

After removing from refrigerated storage, use the vial as soon as possible and within 6 hours. All vials must be protected from light so **must** be stored in the original carton or opaque scheduling container. Vials are to be **used immediately after** preparation (please refer to information at the end of this document).

Document the 'Use By' date and time (24-hour format, e.g. 14:00 hrs) on each vial using indelible pen.

Provide a vial and dose syringe stickers/labels with corresponding 'Use By' to the prepper.

Preppers are to work with one vaccine vial at any one time.

At mass vaccination sites, to streamline logistics, any vials removed within an hour period will be assigned a 'Use By' date and time based on the beginning of the hour (i.e. removed at 08:15 hours, expires 14:00 hours)

Where multiple vials are removed from the fridge at one time, an 'AstraZeneca COVID-19 vaccine stock removed from fridge label' (Example 2) will be assigned to the stock in a designated scheduling container and each vial will subsequently be marked with corresponding 'Use By' date and time.

Consumables Required for Each AstraZeneca MDV Prepared:

- 19-21 gauge bevelled needles
 - 8 or 10 x 23-gauge (or 25-gauge) x 25mm (or 38mm for obese patients) needles
 - 8 or 10 x 1mL LuerSlip or LuerLock syringe
- OR
- 8 to 11 x 1mL low dead space syringe with integrated 23g x 25mm needle
 - 8 to 11 x single use 70% alcohol swabs
 - 9 to 12 x dose syringe stickers/labels (1 extra for black bag) (refer to sample 3)
 - 1 x injection tray (large / 500mL)
 - 1 x black bag to protect dose syringes from light
 - Slip of paper to indicate number of doses prepared and on which to document administration or wastage (Example 4).

Drawing-up and Labelling Dose Syringes:

Before starting, ensure the following are completed:

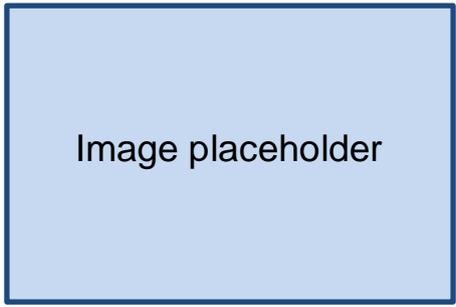
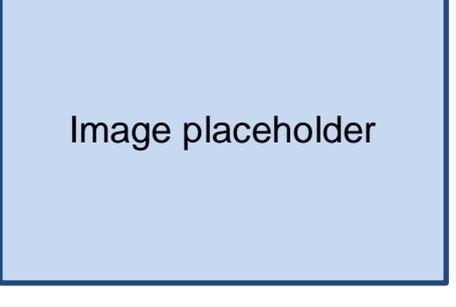
Ensure each multi-dose vial is clearly labelled with the 'Use By' date and time. Check 'Use By' on the label of the vaccine vial has not been exceeded (6 hours out of the fridge).

Perform a visual check of the solution in the vial and check for contamination

- It should be colourless to slightly brown, clear to slightly opaque, and free of any particles. Quarantine the vaccine vial if particulates or discolouration are present.
- Throughout the procedure continue to perform a visual check of the solution and check for contamination. Quarantine the vial and dose syringes if particulates or discolouration are present.

Recommended Step-by-Step Process:

<p>1</p>	<p>Image placeholder</p>	<p>Hand hygiene and don PPE Perform hand hygiene and don appropriate PPE. Prepare aseptic workspace and assemble required consumables.</p>
<p>2</p>	<p>Image placeholder</p>	<p>Wipe vial bung Remove vial cap and wipe bung with a single-use 70% alcohol swab and allow to dry. Discard swab into yellow waste bin.</p>
<p>3</p>	<p>Image placeholder</p>	<p>Attach needle Using aseptic technique, firmly attach drawing up needle to a 1mL syringe. ATAGI strongly recommends using a 19-21 gauge bevelled needle to reduce the risk of coring.</p>
<p>4</p>	<p>Image placeholder</p>	<p>Draw air Using aseptic technique, draw up 0.5mL of air into the empty syringe</p>
<p>5</p>	<p>Image placeholder</p>	<p>Puncture vial Puncture the bung of the vial, equalising pressure by injecting the air into the vial.</p>

<p>6</p>		<p>Invert and draw Invert vial and draw up 0.5 mL of the vaccine into the 1 ml syringe.</p>
<p>7</p>		<p>Remove air bubbles Any air bubbles should be removed prior to removing the needle from vial to avoid losing any vaccine dose. Check volume withdrawn is exactly 0.5mL.</p>
<p>8</p>		<p>Withdraw needle and insert new syringe Upon completion of drawing up a dose (where using the 19-21 gauge needle), maintaining sterility, disconnect drawing up needle and firmly attach 23 gauge (or 25 gauge) 25mm needle to syringe. In the event of a needle stick injury, the needle and syringe must be quarantined, and incident recorded.</p>
<p>9</p>		<p>Dose syringe into tray Place single dose syringe into injection tray Vaccine drawn into prepared dose syringe should be used as soon as practical. There is data supporting stability of vaccine doses after withdrawal into a syringe for up to 6 hours at room temperature (as reflected in the AstraZeneca COVID-19 vaccine product information). However, ATAGI recommends that, as much as possible, pre-drawn doses be used within an hour to minimise any remote potential risk of infection.</p>

		<p>Where doses are administered one after another (e.g. immunisation clinics, including general practice):</p> <p>Repeat steps 2 (including swabbing bung) to 9 a further seven or nine times to produce 8 or 10 dose syringes.</p> <p>Each time the vial bung is punctured, ensure that each re-puncture occurs at a different site on the bung.</p> <p>If low dead space syringes and needles are used, a further dose may be attempted.</p> <p><i>After first opening, use the vial within 6 hours when stored at room temperature (up to 30°C).</i></p> <p>Where doses are not administered immediately one after another (e.g. in many general practices):</p> <p>Each dose should be withdrawn and then administered to a recipient before another dose is withdrawn from the vial for the next recipient.</p> <p>If any doses remain in the vial, refrigerate the vial between +2°C and +8°C immediately after completion of vaccine draw-up.</p> <p><i>After first opening, use the vial within 48 hours when stored in a refrigerator (2°C to 8°C).</i></p>
<p>10</p>		<p>Apply a red cap to last syringe if less than 0.5ml/discard</p> <p>If the amount of vaccine able to be drawn into the final syringe cannot provide a full dose of 0.5 mL, it is not to be used. Remove needle from the under-filled syringe and discard needle into an approved sharps bin.</p> <p>Either: Apply red cap or discard in clinical waste.</p> <p>If less than the expected number of doses (8 or 10) has been achieved, report as a wastage event.</p>
<p>11</p>		<p>Complete syringe label</p> <p>Fill out 'prepared dose syringe label' (Example 3) with 'Use by' Date and time (i.e. 6 hours after vial removed from fridge – same expiry indicated on the vial).</p> <p>Apply a label to every full dose syringe and place in injection tray with empty vial.</p> <p>Visually inspect the syringes for particles and leaks. Quarantine syringe if observed.</p>

12		<p>Protect from light</p> <p>Place the injection tray and its contents in a black bag to protect from light.</p> <p>Label black bag with a completed 'prepared dose syringe label' (Appendix 3).</p> <p>Prepare a slip of paper (Example 4) for immunisers to document dose administration or wastage. Cross off relevant doses not achieved from the vial. Add to black bag.</p>
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ATAGI statement on AstraZeneca COVID-19 vaccine:

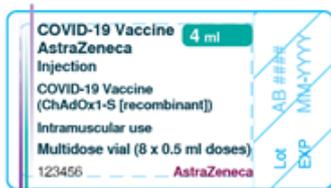
ATAGI released an updated statement on 8 April 2021 regarding safety concerns and the AstraZeneca COVID-19 vaccine. It can be viewed via the link below:

<https://www.health.gov.au/news/atagi-statement-on-astrazeneca-vaccine-in-response-to-new-vaccine-safety-concerns>

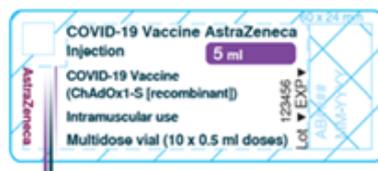
Label Examples:

The following examples display the labels which relate to the above-mentioned step-by-step Astra Zeneca multi-dose vial preparation. Vaccination clinics services may have their own labelling system. This information is to be used as a guide only.

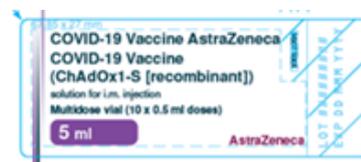
Example 1: Manufacturers labels



Imported 10 x 8 Dose Vials



Imported 10 x 10 Dose Vials



Local 10 x 10 Dose Vials

Example 2: AstraZeneca COVID-19 vaccine stock removed from fridge label

AstraZeneca COVID-19 vaccine stock removed from fridge

Preparation Quantity: _____ (vials in scheduling container)

Manufacturer Batch No: _____

Manufacturer Expiry date: __/__/__

	Date	Time
Removed from refrigerator:	__/__/__	: hrs
↓ 6 hours ↓		
Use by:	__/__/__	: hrs

Vaccine Inventory Coordinator: _____

Example 3: Prepared dose syringe label

AstraZeneca COVID-19 Vaccine (ChAdOx1-S) Syringe volume 0.5mL for IM injection	Use within 6 hours of vial removal from the fridge USE BY: DD / MM / YY at HH : MM hrs
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Example 4: Slip to document doses prepared, administered, wasted

AstraZeneca COVID-19 Vaccine (ChAdOx1-S) Syringe vol: 0.5mL for intramuscular injection.						Prepared by:
Initial when given. Cross if wasted. Report wastage in CVMS or to Vaccine Inventory Coordinator						
Dose 1	Dose 2	Dose 3	Dose 4	Dose 5	Bonus <small>(only if LDS used)</small>	
Dose 6	Dose 7	Dose 8	Dose 9	Dose 10		

Example 5: AstraZeneca COVID-19 vaccine stock returned to fridge label

AstraZeneca COVID-19 vaccine stock returned to fridge

Quantity: _____ (vials in scheduling container)

Manufacturer Batch No: _____

Manufacturer Expiry date: / /

	Date	Time
Removed from refrigerator:	<u> </u> / <u> </u> / <u> </u>	: hrs
Returned to refrigerator:	<u> </u> / <u> </u> / <u> </u>	: hrs
Cumulative total not more than 6 hours		
Duration of room temperature exposure:		: hrs

Bung punctured: Yes / No

	Date	Time
Bung punctured	<u> </u> / <u> </u> / <u> </u>	: hrs
↓ 48 hours ↓		
Use by:	<u> </u> / <u> </u> / <u> </u>	: hrs

Initials Person 1: _____ Person 2: _____

Example 6: Quarantine Labels

Quarantine

DO NOT USE!!

Quantity: vials / syringes (circle)

Manufacturer Batch No:

Manufacturer Expiry date: / /

Identify cause (Circle): Past Expiry
 Damaged
 Contaminated
 Other:

Merlin transaction ID: (adjustment minus)

Initials Person 1: Person 2:

More Information and Resources:

The Victorian COVID-19 vaccination guidelines, appendices and resources are available online:

- <https://www.coronavirus.vic.gov.au/victorian-covid-19-vaccination-guidelines>
Compliance with the most current version of these guidelines is a condition of the Public Health Emergency Orders, and at present, the guidelines are being updated weekly. Please ensure you are using the most up-to-date version.
- Commonwealth Department of Health COVID-19 information: health.gov.au/covid19-vaccines
- Public Health Emergency Order (PHEOs) and Secretary's Approval: <http://www.gazette.vic.gov.au/gazette/Gazettes2021/GG2021S080.pdf>
- Victorian Department of Health COVID-19 vaccine information: coronavirus.vic.gov.au/vaccine
- Victorian Department of Health COVID-19 vaccine research hub: coronavirus.vic.gov.au/research-hub-coronavirus-covid-19-vaccine
- Victorian Department of Health COVID-19 vaccine information for health care workers: coronavirus.vic.gov.au/information-health-care-workers-coronavirus-covid-19-vaccine
- Adverse events following immunisation reporting in Victoria: health.vic.gov.au/public-health/immunisation/adverse-events-following-immunisation-reporting

Contact Us:

For more information on the rollout of the COVID-19 vaccines in Victoria, contact the Victorian Department of Health COVID-19 Vaccination Preparedness Unit by emailing COVIDvaccination@dhhs.vic.gov.au <COVIDvaccination@dhhs.vic.gov.au>.

For assistance with workforce surge requirements, contact COVIDstaffing@dhhs.vic.gov.au.

To receive this document in another format, phone 1300 651 160, using the National Relay Service 13 36 77 if required, or email COVIDvaccination@dhhs.vic.gov.au

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