1. **Purpose**

This SOP describes the process for preparation of a **ready to administer** 0.3mL syringe of Comirnaty JN.1 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) bretovameran (Comirnaty **10 (JN.1) ready to use)** prior to immediate administration.

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| --- | --- |
| Different strengths / formulations of Comirnaty vaccine are available. Ensure the correct procedure is selected for the strength / formulation required. This SOP is for use with Comirnaty **10 (JN.1) ready to use** with the following label format:   |  |

1. **Scope**

This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration.

1. **Responsibility**

Staff performing any stage of the preparation of the vaccine are responsible for following this procedure.

The [insert lead Clinician title / responsible Pharmacist] must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Direction (PGD), National Protocol, Patient Specific Direction (PSD) or other appropriate legal mechanism. In addition, the lead Clinician / responsible Pharmacist must ensure that the staff groups who are undertaking the processes are those defined as eligible to do so.

1. **Procedure**
	1. Prepare the workstation for use:
		* + ensure the preparation workstation is clear and free from any other vials of vaccine.
			+ ensure a yellow lidded sharps bin with sufficient free capacity and an indelible pen are available.
			+ clean workstation with a disinfectant wipe and discard into a clinical waste bin.
	2. [Insert statement on local practice for wearing of aprons and other PPE / sanitising hands / donning gloves for preparing injectable medicines]
	3. When ready to begin preparation select one vial of Comirnaty **10 (JN.1) ready to use** vaccine.
		1. If working with vials stored in a refrigerator:
* If there is more than one batch of vaccine vials, use the one with the shortest expiry
* Check the post thaw expiry date on the carton has not been exceeded.
* Remove a single vial and close the carton.
	+ 1. If working with vials from a cool box at 2 to 8OC:
			- Check the vial is within the post-thaw expiry date by checking the label on the vial transport container. Refer to SOP HCV 6: *Use of cool boxes to transport Covid-19 vaccines to end user locations.*
			- Remove a single vial and close the lid of the cool box.
		2. Assemble the following materials required to prepare syringes:
			- Comirnaty **10 (JN.1) ready to use** vial X 1
			- 1mL syringe with integrated needle X1
			- Sterile single use 70% alcohol swab x 1
		3. Check the identity of the vial. This procedure is intended for use with Comirnaty **10 (JN.1) ready to use** vaccine. Check the label on the vial selected matches the image below:

 

* + 1. Gently mix by inverting the vial 10 times, DO NOT shake. One inversion requires the vial to be fully rotated back to an upright position. Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
		2. Remove the blue vial dust cover.
	1. Prepare the syringe
		1. Check the label again, to ensure the label on the vial selected matches the image below:

 

* + 1. Inspect the vial visually for foreign particulate matter and/or discoloration prior to administration. If particulate matter or discolouration are present, the vaccine should not be administered.

N.B. After mixing the vaccine should present as a white to off-white dispersion with no particulates visible.

* + 1. Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.
		2. Using aseptic technique, draw up **0.3mL** of the vaccine using a new 1mL syringe with integrated 23g needle.

N.B.

* A 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients.
* If using a syringe with an auto retracting needle depressing the plunger will cause the needle to retract prematurely.
	+ 1. Adjust to remove air bubbles with the needle still in the vial to avoid loss of vaccine.
		2. Check volume withdrawn is **0.3mL. [May require independent 2nd check depending on local policy]**
		3. Visually inspect the syringe for foreign particulate matter and leaks. Discard if these are observed.
		4. The newly filled syringe must be used for immediate administration. **[Local risk assessment may be required to manage risk of needle stick injury when handling unsheathed needles]**
		5. Immediately discard the used vaccine vial into a yellow lidded sharps bin.
	1. Dispose of outer cartons by defacing using permanent black marker pens and placing in the general waste stream. Note: the packaging can be flattened easily. For mass vaccination centres packaging must be stored in a secure container(s) and shredded on-site.
1. **Document history**

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| --- | --- | --- | --- |
| **Date** | **Version** | **Section** | **Details** |
| 10/09/2024 | 1.0 | All | This is the first version published.  |

1. **References**

[Comirnaty Omicron JN.1 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)](https://www.medicines.org.uk/emc/product/15836/smpc)

1. **Supporting Documents**

SOP HCV 6: Use of cool boxes to transport Covid-19 vaccines to end user locations.