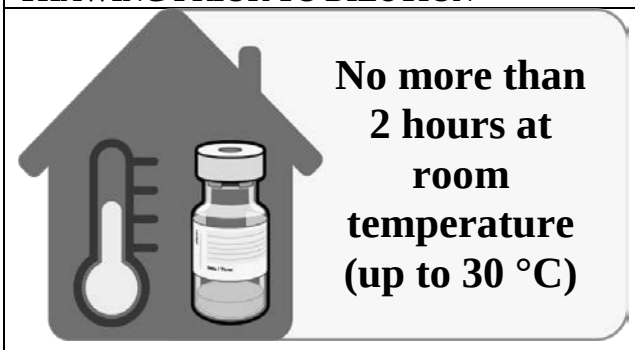
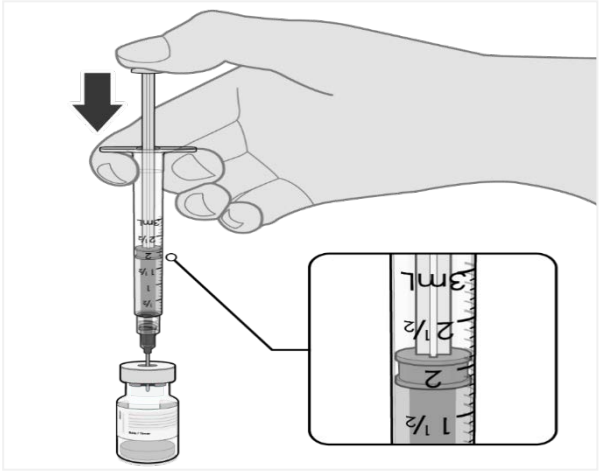
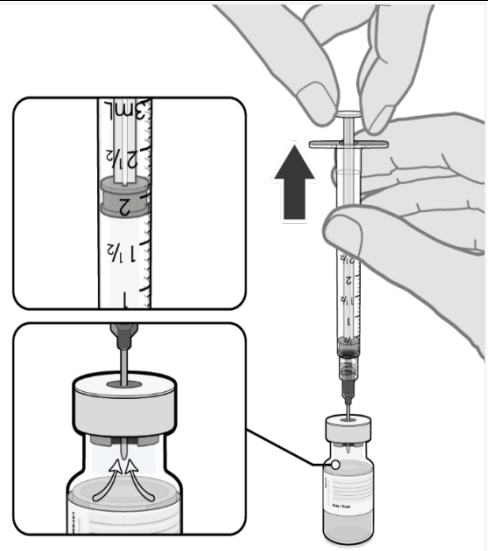
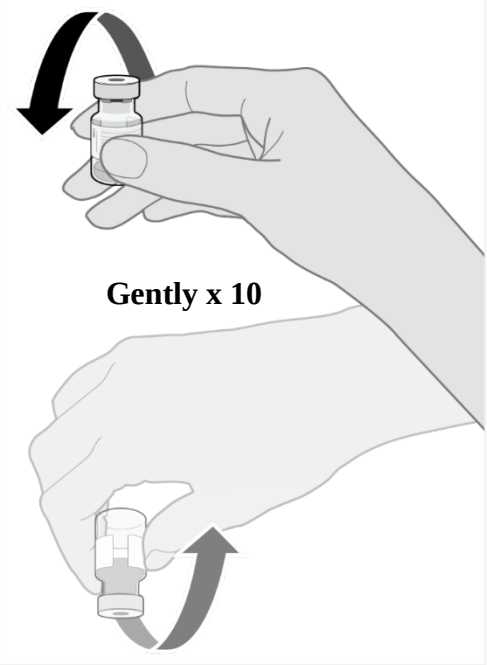
6.6 Special precautions for disposal and other handling

Handling instructions

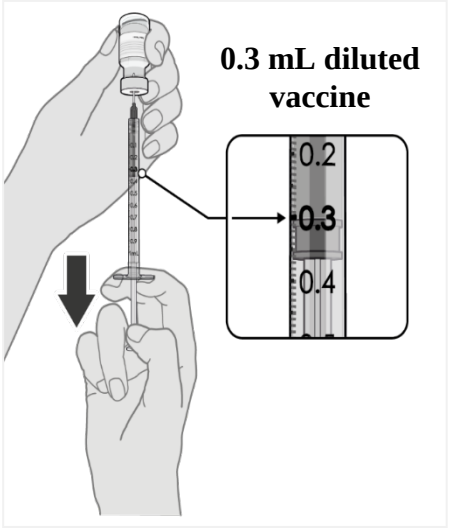
Comirnaty should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

<table>
<tr><td colspan="2">THAWING PRIOR TO DILUTION</td></tr>
<tr><td> 
</td><td>• The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
• Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.</td></tr>
<tr><td colspan="2">DILUTION</td></tr>
<tr><td> 

1.8 mL of 0.9% sodium chloride injection</td><td>• The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.</td></tr>
</table>

 **Pull back plunger to 1.8 mL to remove air from vial**	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.
 **Gently x 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.

<table>
<tr>
<td> 

Record appropriate date and time.
Use within 6 hours after dilution</td>
<td>• The diluted vials should be marked with the appropriate date and time.
• Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.</td>
</tr>
<tr>
<td colspan="2">PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY</td>
</tr>
<tr>
<td> 
</td>
<td>• After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
• Withdraw 0.3 mL of Comirnaty.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
• Each dose must contain 0.3 mL of vaccine.
• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
• Discard any unused vaccine within 6 hours after dilution.</td>
</tr>
</table>

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

This leaflet was last revised in {MM/YYYY}

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine. The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Scan the code with a mobile device to get the package leaflet in different languages.

URL: www.comirnatyglobal.com

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This package leaflet is available in all EU/EEA languages on the European Medicines Agency website.

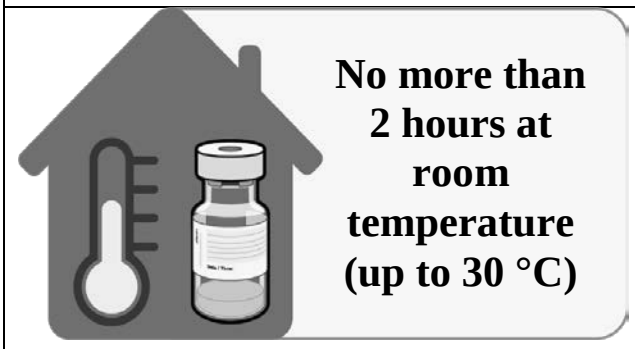
The following information is intended for healthcare professionals only:

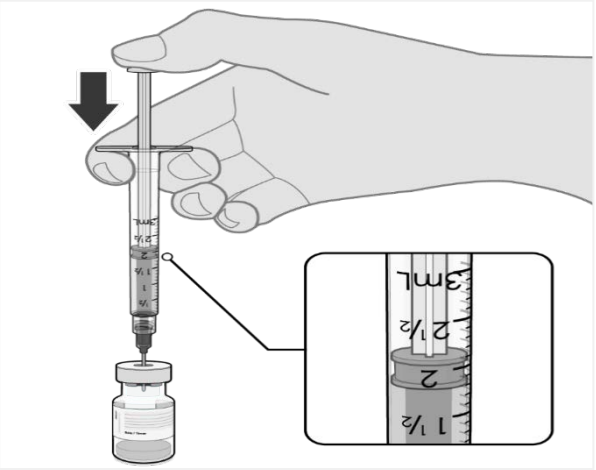
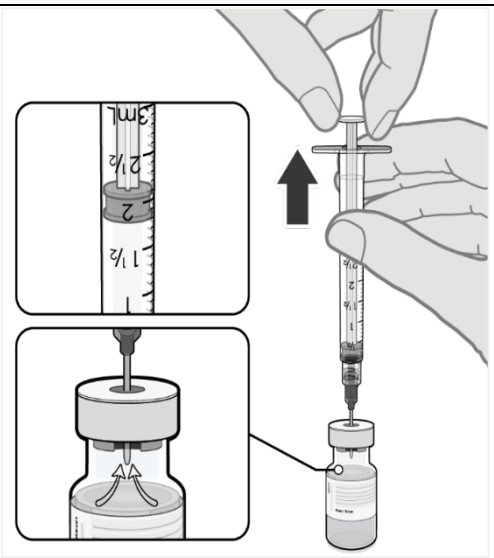
Administer Comirnaty intramuscularly after dilution as a course of 2 doses (0.3 mL each) 3 weeks apart.

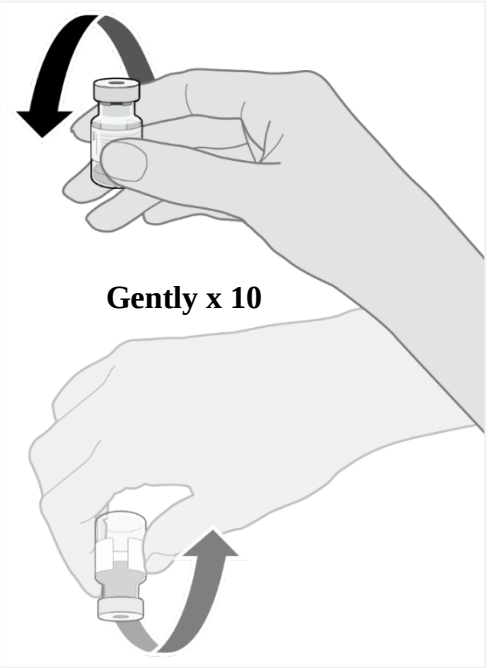
Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

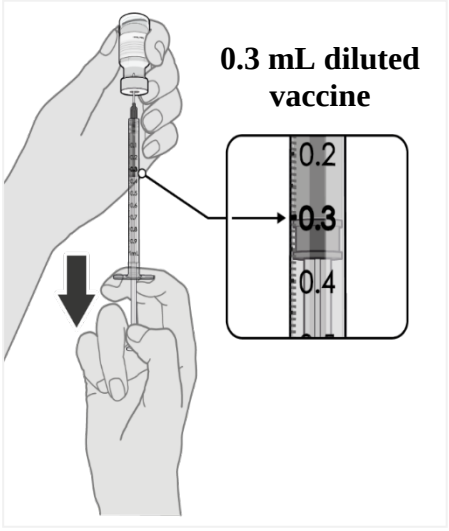
Handling instructions
Comirnaty should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

THAWING PRIOR TO DILUTION	
	• The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use. • Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

DILUTION	
 **1.8 mL of 0.9% sodium chloride injection**	• The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
 **Pull back plunger to 1.8 mL to remove air from vial**	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.

	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.
 **Record appropriate date and time. Use within 6 hours after dilution**	• The diluted vials should be marked with the appropriate date and time. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY



- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty.

  Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

  If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
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