MODERNA BIOTECH SPAIN, S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

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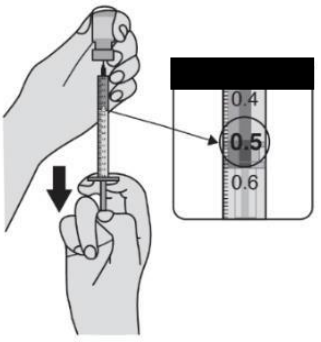
Correct dosing of Spikevax bivalent Original/Omicron booster vaccines[1]

MODERNA BIOTECH SPAIN, S.L. (Moderna) in agreement with the European Medicines Agency (EMA) and the HPRA would like to inform you of the following:

Moderna has received reports of accidental underdosing of the Spikevax bivalent booster vaccines, where a 0.25 mL dose (equivalent to 25 mcg) was administered instead of 0.5 mL (50 mcg). In most cases, underdosing was due to dose confusion, since the booster dose volume for the original monovalent Spikevax vaccine was 0.25 mL (equivalent to 50 mcg).

- **Spikevax bivalent Original/Omicron booster vaccines** have recently been approved by EMA for use in individuals 12 years of age and older**. The correct dose is 0.5 mL (50 mcg).**

Administration of the correct dose of a Spikevax bivalent vaccine:

Eligible recipient **12 years of age and older** receives a **0.5 mL** dose vaccine. Indication: for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older who have previously received at least primary vaccination against COVID-19.	 **bivalent - Spikevax booster** **≥12 years:** **0.5 mL dose**
The appropriate Spikevax bivalent vaccine Summary of Product Characteristics and package leaflet can be found via the QR code on the vial label and carton. https://www.ModernaCovid19Global.com	

Detailed information on this medicinal product is available on the websites of the European Medicines Agency http://www.ema.europa.eu and of the Health Products Regulatory Authority www.hpra.ie.

Reporting of suspected adverse reactions

Healthcare professionals are asked to report any suspected adverse reactions via the HPRA Pharmacovigilance website; www.hpra.ie including the vaccine brand and batch/Lot number if available.

[1] Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection and Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection

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Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

Company contact points:

Telephone: 1800 800 354

Email: EMEAMedinfo@modernatx.com

Sincerely,

Cesar Sanz Rodriguez
Vice President, Medical Affairs
Europe and Switzerland