11-11-2022

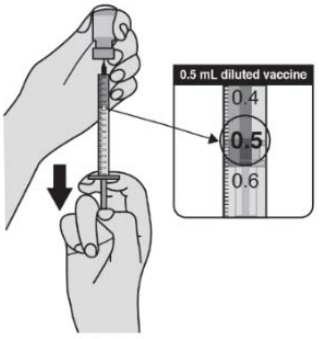
Correct dosing of Spikevax bivalent booster vaccines[1]

MODERNA BIOTECH SPAIN, S.L. (Moderna) in agreement with the European Medicines Agency (EMA) and the Italian Medicine Agency 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 µg) was administered instead of 0.5 mL (50 µg). In most cases, underdosing was due to dose confusion, since the booster dose volume for the original monovalent Spikevax vaccine used earlier in 2022 was 0.25 mL (equivalent to 50 µg).

- **Spikevax bivalent 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 µg).**

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 website of the European Medicines Agency http://www.ema.europa.eu and of the Italian Medicines Agency http://www.aifa.gov.it.

Reporting of suspected adverse reactions

[1] Spikevax bivalent Original/Omicron BA.1 and Spikevax bivalent Original/Omicron BA.4-5

Healthcare professionals are asked to report any suspected adverse reactions via the national spontaneous reporting system https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse, including batch/Lot number if available.

Sincerely