

8 January 2021 EMA/708350/2020

Extra dose from vials of Comirnaty COVID-19 vaccine

EMA's human medicines committee (CHMP) has recommended updating the product information for Comirnaty to clarify that each vial contains 6 doses of the vaccine.

In order to extract six doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be enough of the vaccine to extract a sixth dose from a vial.

If the amount of vaccine remaining in the vial after the fifth dose cannot provide a full dose (0.3 ml), the healthcare professional must discard the vial and its contents. There should be no pooling from multiple vials to make up a full dose, and any unused vaccine should be discarded 6 hours after dilution. Further information on all the steps for using Comirnaty is available in the updated product information.

Comirnaty is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 16 years and older. It was authorised in the EU on 21 December 2020.

Information for healthcare professionals

- After dilution, it is possible to obtain six doses from a vial if you use low dead-volume (≤35 μL) syringes and/or needles for all doses.
- Discard the vial and its contents if the amount of vaccine left in the vial is not enough for a full sixth dose (0.3 ml).
- Do not pool from multiple vials to make up an extra dose.
- Discard any unused vaccine 6 hours after dilution.
- Read the product information for full instructions.



More about the vaccine

Comirnaty is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 16 years and older.

It contains a molecule called messenger RNA (mRNA) with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19. The vaccine works by preparing the body to attack the spike protein on the surface of SARS-CoV-2.

More information is available on the <u>vaccine's page</u> on EMA website.