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Clarification of Comirnaty dosage interval

EMA's human medicines committee (CHMP) has updated the product information for the COVID-19 vaccine Comirnaty to clarify its position on the interval between the first and second dose.

The product information (section 4.2 and package leaflet) now recommends the administration of the second dose 3 weeks after the first dose. Previously, the product information stated that the interval should be "at least 21 days".

The product information (section 5.1) already states that the participants whose data was used to calculate efficacy received their second dose within 19 to 42 days after their first dose. A sentence has been added with the information that 93.1% of these participants received the second dose 19 to 23 days after the first dose.

There are currently no clinical data on the efficacy of the vaccine when administered beyond intervals used in the clinical trial.

Full information for patients and healthcare professionals is available in the updated product information.

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 vaccine's page on EMA website.

More about the procedure

The product information for Comirnaty was updated in a type IB variation. The review has been carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's opinion. The CHMP opinion has immediately been followed by a final legally binding European Commission decision applicable in all EU Member States.

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