Comirnaty/Spikevax 3. annos ja lääkeviranomainen

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Anneli Lauhio

Ylilääkäri

Dos, sisätautien ja infektiosairauksien erikoislääkäri

Kliinisfarmakologinen yksikkö

Lääkevalmisteiden arviointiprosessi

Fimea

Euroopan lääkeviraston (EMAn) ihmislääkevalmiste-komitean (CHMP) suositus koronarokotteen tehosteannoksista, lokakuu 2021

- **Comirnaty 3. tehosteannos voidaan antaa**
  - **18-vuotiaille** ja sitä vanhemmille **puoli vuotta** toisen annoksen jälkeen

Euroopan lääkeviraston (EMAn) ihmislääkevalmiste-komitean (CHMP) suositus koronarokotteen tehosteannoksista, lokakuu 2021

Henkilöille, joilla on **vakavasti heikentynyt immuunijärjestelmä**, voidaan antaa **3. tehoste** koronarokoteannos **vähintään 28 päivää** toisen annoksen jälkeen.

Suositus koskee sekä **Comirnaty-** että **Spikevax** –rokotteita

Muutoin Spikevaxin osalta EMA antaa siitä suosituksensa myöhemmin.

EMA press 4.10.2021

- At national level, public health bodies may issue official recommendations on the use of booster doses, taking into account emerging effectiveness data and the limited safety data.
- The risk of inflammatory heart conditions or other very rare side effects after a booster is not known and is being carefully monitored.
    - As for all medicines, EMA will continue to look at all data on the safety and effectiveness of the vaccine.
- The implementation of vaccination campaigns in the EU remains the prerogative of the national immunisation technical advisory groups (NITAGs) guiding the vaccination campaigns in each EU Member State.
    - These bodies are best placed to take into account the local conditions, including the spread of the virus (especially any variants of concern), the availability of vaccines and the capacities of national health systems.

Comirnaty SmPC (valmisteyhteenveto 4.10.2021, CHMP)

- 1 dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
- Severely immunocompromised aged 12 years and older A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised (see section 4.4).
- **Paediatric population**

  The safety and efficacy of Comirnaty in paediatric participants aged less than 12 years have not yet been established. Limited data are available.
- **Elderly population**

  No dosage adjustment is required in elderly individuals ≥ 65 years of age. The safety and Immunogenicity of a booster dose (third dose) of Comirnaty in individuals 65 years of age and older is based on safety and immunogenicity data in adults 18 to 55 years of age.
- **Myocarditis**

  The risk of myocarditis after a third dose of Comirnaty has not yet been characterised.

Comirnaty SmPC (valmisteyhteenveto 4.10.2021, CHMP)

Immunocompromised individuals

The efficacy and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Comirnaty may be lower in immunocompromised individuals. The recommendation to consider a third dose in severely immunocompromised individuals is based on limited serological evidence from a case-series in the literature from the clinical management of patients with iatrogenic immunocompromisation after solid organ transplantation (see section 4.2).

Duration of protection

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials

Immunogenicity in participants 18 years of age and older

After booster dose (third dose) effectiveness of a booster dose of Comirnaty was based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). In Study 2, analyses of NT50 1 month after the booster dose compared to 1 month after the primary series in individuals 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster vaccination demonstrated noninferiority for both geometric mean ratio (GMR) and difference in seroresponse rates. Seroresponse for a participant was defined as achieving a ≥ 4-fold rise in NT50 from baseline (before primary series). These analyses are summarized in Table 5.

Spikevax SmPC (valmisteyhteenveto, pvm 4.10.2021, CHMP)

One dose (0.5 mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).

Severely immunocompromised aged 12 years and older

A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised (see section 4.4).

Myocarditis and pericarditis

Very rare cases of myocarditis and pericarditis have been observed following vaccination with Spikevax. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

HUOM! Pohjoismainen uusi data - THL tiedote

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Immunocompromised individuals

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- The recommendation to consider a third dose (0.5 ml) in severely immunocompromised individuals (see section 4.2) is based on limited serological evidence with patients who are immunocompromised after solid organ transplantation.

Kiitos !