

Informed consent for a booster vaccine to a young person aged 12 to 17

With this document you confirm that your child may receive a **booster vaccine** against COVID-19, after having **informed** yourself **well**. Here we summarise the most relevant information about this booster vaccination for you. You can also find it on www.laatjevaccineren.be/booster-12-17-jaar. Please also consult this website for the latest information. You can always ask your family doctor for advice. At the vaccination centre you can also ask the centre doctor or nurse any additional questions.

The booster vaccination is **voluntary**.

What is a booster vaccine?

A booster vaccination is a **complementary vaccination** after the primary vaccination intended at boosting protection against infection and disease.

Your child can therefore receive a booster or complementary vaccination if **they have first had a primary vaccination**. In Belgium, this primary vaccination was given to 12 to 17-year-olds by means of two doses of the **Pfizer** produced vaccine. A booster vaccination can be administered **as from 4 months** after the second primary vaccination.

A booster vaccine **completes the vaccination cycle**. Also with vaccines against other diseases it is common that several doses are needed to complete the vaccination cycle.

Why are we offering a booster vaccine?

Several studies on adults have shown that the effect of the primary vaccination **diminishes** with time. The protection against COVID-19 infection (with or without symptoms) provided by the primary vaccination starts to decline a few months after the first 2 doses. In Flanders, we note that the number of infections among young people between the ages of 12 and 17 is increasing, which indicates that the protection against COVID-19 infections provided by the primary vaccination, is also diminishing amongst our Flemish youngsters.

Considering the diminishing effectiveness on the one hand, and the heavy circulation of COVID-19 variants in the group of 12-17-year olds on the other, a booster vaccination is worthwhile. Scientific data on booster vaccine administration to 12-17-year olds show that such a booster vaccination is effective and safe (see below).

Which vaccine?

In Flanders only the **Pfizer** produced vaccine (Comirnaty 30 µg) will be used as a booster. This is **the same vaccine in the same dosage** as the first 2 primary vaccinations for 12-17-year olds and it is already being given as a booster vaccine to young people aged 12 to 17 with immune system disorders. It is an **mRNA vaccine** (more about the effect of mRNA vaccines on <https://www.laatjevaccineren.be/covid-19-vaccins/species-vaccins>). The package leaflet for this vaccine is available on the FAMHP website (www.fagg.be).

Which authorities have or have not given approval for, or advice on this booster vaccine?

- **EMA** is the European public authority that evaluates the effectiveness and safety of medicines before they are put on the European market. Pfizer's COVID-19 vaccine has been approved by EMA for primary vaccination of 12-17-year olds. The use of the same vaccine as a booster vaccine is **has been approved by the EMA on February 24th 2022**.
- The **Superior Health Council of Belgium (SHC)** is waiting for a ruling by EMA before issuing an advice. The SHC announced on 28 January that they still had **too little information** at that time to be able to advise on vaccination.

- The US **Food and Drug Administration** (FDA) has already given **approval** for this booster vaccine. The FDA is the American counterpart of EMA.
- In **various European countries**, the booster vaccination is already being administered to children between 12 and 17 years of age, such as Germany, France, Italy, Luxembourg, Austria, Poland, Portugal, the Czech Republic and Switzerland.
- Also **outside Europe** several countries have already approved the Pfizer vaccine as a booster vaccine for this age group, for example the United States, Israel, Singapore, Qatar and the Philippines.

What do we already know about the effect of the booster on 12-17-year olds?

Israel was the first country to organize a booster vaccination for 12-17-year olds with the Pfizer “Comirnaty” (30 µg) vaccine. The **infection level** amongst recently boosted youngsters was **significantly lower** than amongst youngsters of the same age group who had received their 2nd dose 5-6 months before, but no booster. However, this still concerned infections with the **Delta variant** of the COVID-19 virus.

In the meantime, the **Omicron variant** is dominant in our country. At present, there are **no data** yet regarding the protection provided to 12-17-year olds by the booster vaccination against Omicron variant infections or against development of serious disease after infection.

Among **adults** it has been shown that a booster vaccination reduces the risk of Omicron variant infection leading to illness or hospitalisation. There is no reason to believe that this would be any different for 12-17-year olds.

Is a booster vaccination safe for 12-17-year olds?

Other countries have already started booster vaccination on 12-17-year olds and are monitoring its safety. Current data on booster vaccine safety are **reassuring**. Among **adults** the number of side effects reported after such booster is comparable or lower than after the previous dose. Recent data from the US confirm this finding for booster vaccination of 12-17-year olds.

The **most common side effects** of the corona vaccines are a sore and sometimes somewhat swollen (red) spot on the arm where the shot was placed, fatigue, headache, muscle aches and fever. Sometimes lymph nodes are swollen. The same side effect occurs with the booster shot. These symptoms are usually mild to moderate and show up within a few days of vaccination. A **known rare side effect** of mRNA vaccines, especially in boys, is an increased risk of **myocarditis** (heart muscle inflammation). This condition is treatable and has a mild course.

There are only few **data** available on the occurrence of this side effect after a booster dose with 12-17-year olds. In Israel, 2 cases of mild myocarditis were reported after administration of 41,610 booster doses to 12-15-year olds.

Where and when can the booster vaccination be given?

Your regional vaccination centre will provide the booster vaccination. Check on www.laatjevaccineren.be or on your vaccination centre’s website for practical arrangements.

INFORMED CONSENT

By signing this document you give your informed consent that your child may receive a booster vaccination. If parental authority is exercised by two parents/guardians, the consenting parent confirms that this consent is a **jointly supported and coordinated decision**.

You can **change your mind** at any time before the vaccination **and withdraw the consent**.

I give permission for my child to receive a booster vaccination:

Child’s name:

Child’s national register number/bis number:

Date of the child’s second primary vaccination:

Parent’s name:

Signature and date: