



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## What is known about COVID-19 in children?

COVID-19 is generally mild in children of all ages, although severe cases leading to hospitalisation do occur rarely. Children with an underlying illness are more likely than others to be admitted to hospital.

Current evidence indicates that the currently circulating Omicron variant causes less severe disease than other variants but is more infectious. According to [data from ECDC](#), there had been an increase in the number of cases and hospitalisations of children with COVID-19 in the EU after July 2021, including during the emergence of Omicron.

ECDC has published [interim considerations](#) for vaccinating children 5-11 years old. An update on the effects of Omicron in children will be provided as further data become available.

## Are vaccines effective at preventing COVID-19 in children?

Current evidence indicates that COVID-19 vaccines are as effective in children as they are in adults.

When EMA evaluated [Comirnaty](#) for children from 5 years old and [Spikevax](#) for children from 6 years old, it found that the levels of antibodies against SARS-CoV-2 in children after vaccination were comparable to those in adults.

In addition, available evidence indicates that the immune response to a [booster dose of Comirnaty](#) in adolescents from 12 years of age is at least equal to that in adults.

Data on the effectiveness against the Omicron variant in children are still emerging. However, preliminary [data from adults](#) indicate COVID-19 vaccines remain effective against severe disease and hospitalisation caused by the Omicron variant.

There are currently limited data on how long protection in children lasts.

## How safe are COVID-19 vaccines in children?

Emerging data (including data [from the United States](#) where millions of children are vaccinated) indicate that COVID-19 vaccines are well tolerated in children. EMA will assess these and other real world data as they become available.

Clinical trials previously carried out in children also showed that side effects of these vaccines are usually mild or moderate and go away in a few days. The most common side effects seen in trials are injection site reactions, nausea and vomiting.

Very rare cases of myocarditis and pericarditis (inflammatory conditions affecting the heart) have occurred in adolescents and adults after vaccination with mRNA vaccines. As with myocarditis or pericarditis unrelated to vaccination, these conditions usually resolve following treatment.

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EMA will continue monitoring data on safety in children as vaccinations continue.

### **How did EMA evaluate COVID-19 vaccines for children?**

A company developing a COVID-19 vaccine must have a paediatric investigation plan (PIP) in place before their vaccine is authorised for adults. The plan outlines all the studies the company needs to carry out to support the vaccine's authorisation in children.

EMA has evaluated studies carried out as part of PIPs. These include studies that looked at how well the vaccines triggered an immune response in children compared with adults, as well as safety and efficacy studies in children, involving up to 3,000 participants.

EMA also considered the data from large studies in adults, including studies with up to 44,000 participants, and reports of side effects in adults. These may be relevant for children because of the similarities in how children and adults respond to vaccines.

EMA will continue evaluating data on these vaccines, including large amounts of real-world data on children from around the world.

### **Where can I get advice about vaccinating children against COVID-19?**

In the EU, national authorities advise on vaccinating children as part of national vaccination campaigns in each country. They consider the overall situation in their country and the effects COVID-19 is having on different groups of people.

If you have any questions about vaccinating your child, you can also discuss these with a healthcare professional, particularly if your child has an underlying illness that puts them at higher risk of severe COVID-19.

More information on the use of COVID-19 vaccines, including in children where applicable, is available on the [dedicated webpages](#) for each authorised vaccine.