



## SARS-CoV-2 (COVID-19) vaccination for Acute Leukemia patients

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**NOTE: This is not intended to be medical advice and, as every individual case differs, ALAN recommends you consult your hematologist/clinician if you have questions or concerns.**

**Also, as the situation surrounding COVID-19 and vaccination is evolving rapidly, always refer to your governmental websites.**

### What is COVID-19?

COVID-19 is the disease associated with severe acute respiratory syndrome coronavirus (SARS-CoV-2). SARS-CoV-2 is a new strain of coronavirus that had not been identified in humans prior to December 2019. There are different types of coronaviruses and, although they mostly circulate among animals, some can also infect humans.

The COVID-19 outbreak that started in late 2019 was declared a pandemic by the World Health Organization on 11 March 2020. This is the first pandemic caused by a coronavirus.

### Additional information:

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public>

<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

[https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response\\_en](https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response_en)

<https://vaccination-info.eu/en/covid-19/covid-19-facts>

Live Worldwide COVID-19 Situation: <https://gap.ecdc.europa.eu/public/extensions/COVID-19/covid-19.html#global-overview-tab>

### Vaccination

What type of approval processes did COVID-19 vaccines undergo?

Due to the existing public health emergency, COVID-19 vaccines went through an accelerated development process but were still subject to the rigorous evaluation methods used by the various health authorities. These vaccines were, and are still, evaluated against the same high standards as any other medicine.

It is important to understand that while the approval for the COVID-19 vaccines was accelerated, vaccines with similar mechanisms of action have been in development for years. The current COVID-19 vaccines were developed using existing research.

### Additional information

[https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/how-are-vaccines-developed-authorized-and-put-market\\_en](https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/how-are-vaccines-developed-authorized-and-put-market_en)

<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

<https://www.australia.gov.au/covid19vaccines#>



COVID-19 vaccines: development, evaluation, approval and monitoring: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-development-evaluation-approval-monitoring>

How do the COVID-19 vaccines work?

Vaccines teach our immune system to recognise and protect us from COVID-19 if/when we get infected with the virus.

The BioNTech/Pfizer and Moderna vaccines are mRNA vaccines. These vaccines use genetic material, called mRNA, which, after injection, enters your cells (note: this genetic material does not enter the innermost part of your cells called the nucleus nor your DNA). The cells then translate the mRNA into proteins that look like the proteins found on the surface of the COVID-19 virus. These proteins then enter your bloodstream, where the body recognises them as foreign and generates an immune response. Therefore, if you contract COVID-19 after receiving the vaccination, your body will recognise the virus and be able to respond quickly to fight the infection.

The AstraZeneca/Oxford and Janssen vaccines use a different approach and use something called viral vectors. These vaccines are made using an inactive adenovirus, which serves as a shell to carry DNA genetic material into your cells (note: this genetic material does not enter the innermost part of your cells called the nucleus nor your DNA). This DNA is then made into mRNA and then into proteins that look like the proteins found on the surface of the COVID-19 virus. These proteins then enter your bloodstream where the body recognises them as foreign and generates an immune response. Therefore, if you contract COVID-19 after receiving the vaccination, your body will recognise the virus and be able to respond quickly to fight the infection.

None of these vaccines contain live viruses and there is no risk of catching COVID-19 (or adenovirus) from the vaccine.

**Additional information:**

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html>

<https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work>

<https://youtu.be/0AssZJON2Ls>

COVID-19 vaccines key facts: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-key-facts>

How effective are these vaccines?

It is important to understand that while each vaccine has different efficacy, they all offer protection against hospitalisation and/or death from COVID-19. Also, given the timing, population, and location of where each vaccine was studied, it is impossible to compare their efficacy and judge any one vaccine to be either inferior or superior to any other.

It is also important to remember that a vaccine with lower effectiveness can still save thousands of lives and prevent millions of cases of COVID-19.

Each of the COVID-19 vaccines was tested in thousands of patients of varying ethnicities and some with medical conditions, for example, lung and heart disease. Acute leukemia patients were not specifically included in these clinical trials nor is there any data on the efficacy of these drugs in the acute leukemia population. It has been suggested that these vaccines may be less effective in immunocompromised patients, but this has yet to be proved and this should not be a reason to forgo immunisation.



ALAN recommends you discuss this matter with doctor/hematologist if you have any questions or concerns.

[What COVID-19 vaccines are approved for use in immunocompromised patients?](#)

Despite several vaccine candidates being in phase II/III clinical trials, no current clinical trial of a COVID-19 vaccine has published data on immunocompromised patients. Thus, the efficacy and safety of a SARS-CoV-2 vaccine has not been established in the different immunocompromised patient populations. There are no data that preferentially support one vaccine over another in this or any population.

[Is a third dose needed?](#)

The approved vaccines have shown a high level of efficacy at preventing severe illness from coronavirus. However, the same is not true for people with certain immune conditions, including those living with a rare disease, representing a population of several million European citizens and many more worldwide. Figures show that antibody response after two doses was insufficient in transplant recipients (varied between 17% and 45%), dialysis patients and people taking an immuno-suppressive treatment.

In Europe, France is setting an example by handing out third shots of the two-dose vaccines to cancer and other immunocompromised patients. Israel has also begun offering a third dose of the Pfizer-BioNTech vaccine to people with a compromised or impaired immune response, including cancer patients and transplant recipients, to protect the most vulnerable and prevent hospitalisations and serious illness.

[Will booster doses of COVID-19 vaccines be needed?](#)

It is currently too early to say if booster doses will be needed.

There is not yet enough data to understand how long protection from COVID-19 vaccines lasts, so the need for additional doses of the vaccines is not known.

In addition, the impact of the spread of virus variants needs to be considered.

[Do the COVID-19 vaccines protect against variants?](#)

The scientific community and regulators are closely monitoring how SARS-CoV-2 (the virus that causes COVID-19) changes over time, and how well COVID-19 vaccines can protect people against COVID-19 caused by any new variants of the virus that appear.

The regulators have asked all COVID-19 vaccine developers to investigate whether their vaccine can offer protection against any new variants identified.

[How soon after receiving a vaccine am I considered to be protected? How long does protection last?](#)

With vaccines that require two doses, you are not considered protected until sometime after the second dose. Therefore, it is important to continue to limit your risk of catching or transmitting COVID-19 before you get your second shot.

Also getting the COVID-19 vaccine does not ensure full immunity, therefore, you must still physically distance, wear a mask, and wash your hands. (It is also important to remember that there is not enough data to know how the vaccines reduce transmission of COVID-19 from one person to another.) v

The length of time of protection that each vaccine offers is not yet known but is under investigation.



### What are the side effects of the COVID-19 vaccines?

Studies investigating the COVID-19 vaccine were done on many patients and showed there is a very low risk of serious side effects from all four vaccines. The most common side effects were chills, headache, pain (generalised body pain or at the injection site), fever, nausea, tiredness and/or redness, and swelling at the injection site. Most of the side effects were considered mild or moderate and resolved within a day or two after the vaccination.

On rare occasions, people developed severe allergic reactions (anaphylaxis) soon after receiving a vaccine. Therefore, COVID-19 vaccines should be given under close medical supervision to monitor potential allergic reactions. Anyone with a history of severe allergic reactions can still receive these vaccines, but they should first consult their doctor to discuss the risks and benefits of the vaccine.

For more information ALAN recommends you discuss this matter with your local health authorities and/or your treating physician.

### Can a different vaccine be used for the second dose?

There is not yet enough data on mixing COVID-19 vaccines to enable health authorities to make a definitive recommendation on using a different COVID-19 vaccine for the second dose.

However, there are good scientific grounds to expect such a 'mix and match' approach (officially, a 'heterologous vaccination strategy') to be safe and effective. It has been used successfully with other vaccines.

### How does the COVID-19 vaccine affect treatment for acute leukemia?

There is no evidence that the vaccine will have any interactions with the medicines used to treat acute leukemia. However, some drugs used during intensive treatment may weaken the immune system. As a result, patients undergoing intensive therapy may not respond as well to the COVID-19 vaccine. Despite this, it is still recommended to get the vaccine.

For more information ALAN recommends you discuss this matter with doctor/hematologist to determine their options.

Published recommendations by medical societies.

<https://www.hematology.org/covid-19/ash-astct-covid-19-and-vaccines>

<https://ehaweb.org/covid-19/covid-19-recommendations/>

<https://www.esmo.org/covid-19-and-cancer/covid-19-vaccination>

<https://bsbmtct.org/wp-content/uploads/2021/01/BSBMTCT-SARS-CoV-2-vaccination-statement-12Jan2021-FINAL.pdf>

<https://www.ebmt.org/sites/default/files/2021-01/COVID%20vaccines%20version%203.04%20with%20table.pdf.pdf>

### Which COVID-19 vaccines are approved and where?

Coronavirus vaccine tracker: <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html#pfizer>

Live status

COVID-19 vaccination tracker: <https://gap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab>



Tracking COVID-19 vaccination worldwide: <https://edition.cnn.com/interactive/2021/health/global-covid-vaccinations/>



## APPENDIX EUROPE

### Which COVID-19 vaccines are approved by the European Medicines Agency (EMA)?

There are currently 4 vaccines approved for use by EMA for the prevention of COVID-19 – See Table 1 (Source: EMA, date 26 April 2021 – Table prepared by MPE)

- BioNTech/Pfizer COVID-19 vaccine; for patients aged 12 and older
- Vaxzevria COVID-19 vaccine (previously COVID-19 Vaccine AstraZeneca): for patients aged 18 and older (some countries 18-55 or 18-65)
- Moderna COVID-19 vaccine; for patients aged 18 and older - EMA has started evaluating an application to extend the use of the COVID-19 Vaccine Moderna to include young people aged 12 to 17.
- Janssen COVID-19 vaccine; for patients aged 18 and older



	Pfizer/BioNtech	Moderna	AstraZeneca/Oxford	Janssen
<b>Schedule</b>	2 injections; given 21 days apart	2 injections; given 28 days apart	2 injections; given 4-12 weeks apart	1 injection
<b>Vaccine Type</b>	mRNA	mRNA	modified adenovirus (not a live virus)	modified adenovirus (not a live virus)
<b>Approved age</b>	12+	18+	18+ (some countries 18-55 or 18- 65)	18+
<b>Efficacy</b>	95%	94.1%	70.4%	66.3%
<b>Start of protection</b>	7 days after the second dose of the vaccine	14 days after the second dose	15 days after the second dose	14-28 days
<b>Appropriate for acute leukemia patients?</b>	Yes. Take when/ if recommended to you or available in your country.	Yes. Take when/ if recommended to you or available in your country.	Yes. Take when/ if recommended to you or available in your country.	Yes. Take when/ if recommended to you or available in your country.

**Table 1.** Overview of COVID-19 vaccines currently approved by the European Medicines Agency

### Which additional COVID-19 vaccines are currently being evaluated?

<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-under-evaluation# covid-19-vaccines-under-rolling-review-section>

### Treatments

There are potential COVID-19 treatments that are currently under investigation and/or evaluation

<https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-treatments>



USA

Which COVID-19 vaccines are approved by the Food and Drug Administration (FDA)?

There are currently three vaccines approved for use by FDA for the prevention of COVID-19 – See Figure 1 (Source: FDA, date 27 April 2021)

- [BioNTech/Pfizer COVID-19 vaccine](#); for patients aged 16 and older
- [Moderna COVID-19 vaccine](#); for patients aged 18 and older
- [Janssen COVID-19 vaccine](#); for patients aged 18 and older



Figure 1: Overview of COVID-19 vaccines currently approved by the FDA

**Additional information:**

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>