

Question & Answer

MYELOMA PATIENTS EUROPE

SARS-CoV-2 (COVID-19) Vaccination for Myeloma Patients





Edition: Myeloma Patients Europe (MPE)

Updated: March 2021

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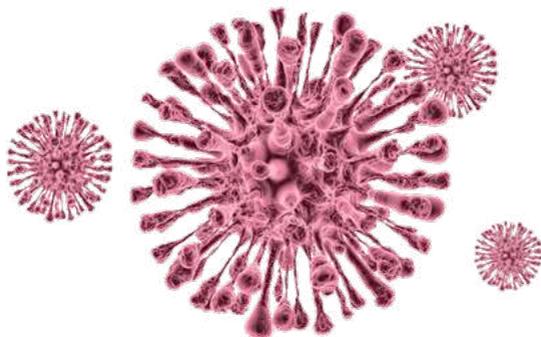
Introduction

The SARS-CoV-2 (COVID-19) pandemic has raised a lot of questions, especially around vaccination. We hope to answer some of the most frequently asked questions about the current approved vaccines in Europe. This is not intended to be medical advice and, as every individual case differs, we recommend you consult your haematologist/clinician if you have further questions or concerns. Also, as the situation surrounding COVID-19 and vaccination is evolving rapidly, MPE will attempt to update this document when new information emerges.

This Q&A provides information on the following:

- The approved vaccines in Europe as of March 2021.
- How the approved vaccines work and how they are administered.
- The side effects and efficacy of the approved vaccines.

If you have any further questions or comments, please email info@mpeurope.org.



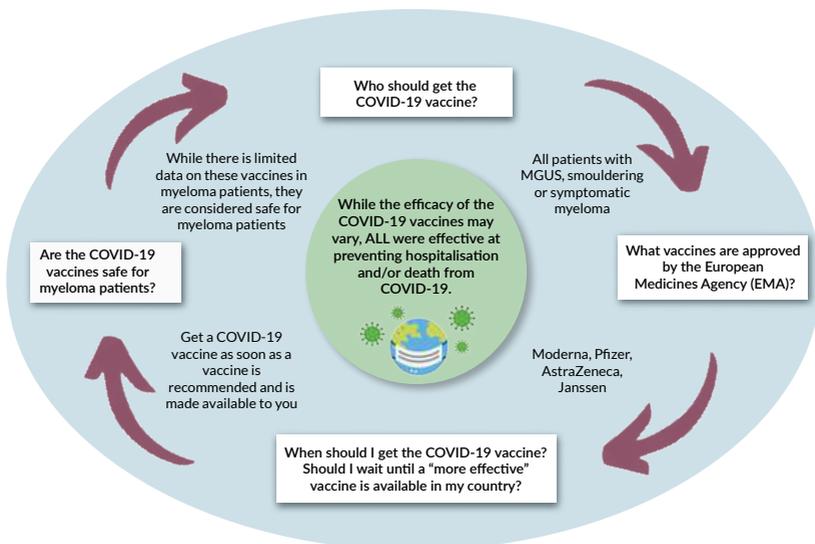
Note:

This is not intended to be medical advice. Please speak with your clinician if you have any questions or concerns about vaccination.

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

There are currently four vaccines approved for use by the European Medicines Agency for the prevention of COVID-19 (see **Table 1** for more information on each vaccine):

- BioNTech/Pfizer COVID-19 vaccine; for patients aged 16 and older
- AstraZeneca/Oxford COVID-19 vaccine; for patients aged 18 and older (some countries 18-55 or 18-65)
- Moderna COVID-19 vaccine; for patients aged 18 and older
- Janssen COVID-19 vaccine; for patients aged 18 and older



Reference: [IMS guidelines](#).

What type of approval processes did these 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 EMA. These vaccines were 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 to the EMA approved COVID-19 vaccines have been in development for years. The current COVID-19 vaccines were developed using existing research.

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.

How are COVID-19 vaccines administered?

The BioNTech/Pfizer, Moderna, and AstraZeneca/Oxford vaccines are given in two doses at specific intervals (see **Table 1** for more information).

The Janssen vaccine is given in one dose (see **Table 1** for more information).

All the injections are usually given into the muscle of the upper arm.

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. The flu shot, for example, has an effectiveness of 40–60%, according to the Centers for Disease Control and Prevention (CDC). However, during 2018–2019, it prevented around “4.4 million influenza illnesses, 2.3 million influenza-associated medical visits, 58,000 influenza-associated hospitalisations, and 3,500 influenza-associated deaths.”^{1,2}



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. Myeloma patients were not specifically included in these clinical trials nor is there any data on the efficacy of these drugs in the myeloma population. It has been suggested that these vaccines may be less effective in myeloma/immunocompromised patients, but this has yet to be proved and this should not be a reason to forgo immunisation.

Of note, although the EMA has approved the AstraZeneca/Oxford vaccine for patients 18 and older, some countries restrict this to patients 18 to 55 or 18 to 65 years of age as there is some concern that this vaccine may be less effective in older patients. Consult your clinician if you have any questions or concerns.

See **Table 1** for a summary of efficacy information for each vaccine.

Do the COVID-19 vaccines protect against variants?

According to the EMA, 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 EMA has asked all COVID-19 vaccine developers to investigate whether their vaccine can offer protection against any new variants, such as those identified in the United Kingdom, South Africa, and Brazil, and to submit relevant data³.

There is some preliminary information on how these vaccines work against variants. A summary of this information can be found in **Table 2**.



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.)

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

See **Table 1** for specifics on the timing of protection for each vaccine.

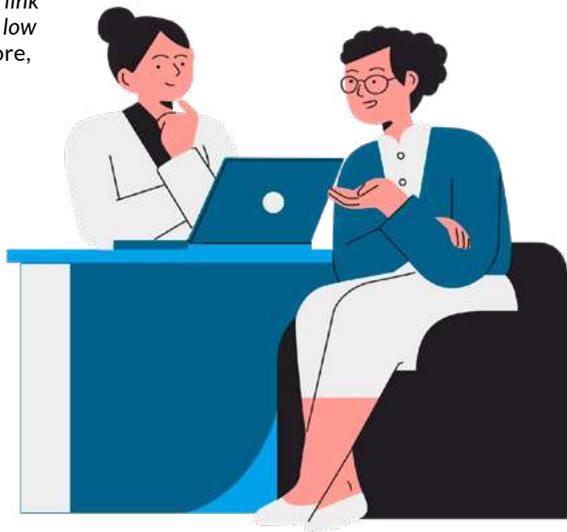
What are the side effects of the COVID-19 vaccines?

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.

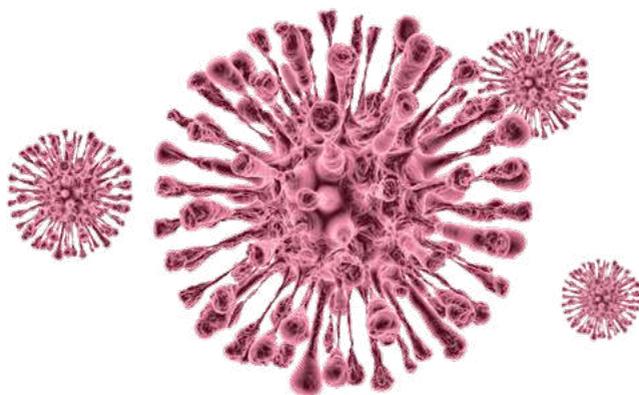
Recently, several European health authorities have temporarily halted administration of the AstraZeneca vaccine out of an abundance of caution given several instances of blood clots and low platelets (cells your body uses to stop bleeding). As of March 18, 2021, however, the **European Medicines Agency (EMA)** stated that *“the benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets.”* Therefore, some countries have restarted vaccination.

For more information MPE recommends you discuss this matter with your local health authorities and/ or your treating physician, especially if you are on certain myeloma medications. The full press release given on 18 March 2021 can be read [here](#).



How does the COVID-19 vaccine affect treatment for myeloma and AL amyloidosis?

There is no evidence that the vaccine will have any interactions with the medicines used to treat myeloma and AL amyloidosis. 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. Patients should consult their doctor/haematologist to determine their options.



ACKNOWLEDGEMENT

Myeloma Patients Europe would like to acknowledge Dr Katja Weisel, from the University Medical Centre Hamburg-Eppendorf in Germany, who provided input about the COVID-19 vaccine situation and its impacts on myeloma and AL amyloidosis patients.

Additional information



	Pfizer/ BioNtech ⁴	Moderna ⁵	AstraZeneca/ Oxford ⁶	Janssen ⁷
Schedule	2 injections; given 21 days apart	2 injections; given 28 days apart	2 injections; given 4-12 weeks apart	1 injection
Vaccine Type	mRNA	mRNA	modified adenovirus (not live virus)	modified adenovirus (not live virus)
Approved for patients ages:	16+ years old	18+ years old	18+ years old <i>(Some countries 18-55)</i>	18+ years old
Efficacy	95%	94.1%	70.4%	66.3%
Start of protection	7 days after the second dose of the vaccine	14 days after the second dose	15 days after the second dose	14-28 days
Appropriate for myeloma patients?	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 (EMA)



	Pfizer/ BioNtech	Moderna	AstraZeneca/ Oxford	Janssen
UK Variant (B.1.1.7)	94%	Unknown	74.6%	Unknown
South Africa Variant (B.1.351)	Unknown	Unknown	To be confirmed. Preliminary data shows around 10%	57%
Brazil Variant (P.1)	Unknown	Unknown	Unknown	Unknown
French Variant (Unknown)	Unknown	Unknown	Unknown	Unknown

Table 2. Preliminary data available for each vaccine's efficacy on the COVID-19 variants.^{8,9}



References

1. Centers for Disease and Prevention. Estimated Influenza Illnesses, Medical visits, and Hospitalizations Averted by Vaccination: <https://www.cdc.gov/flu/vaccines-work/burden-averted.htm?web=1&wdLOR=c6CCF2F0C-9782-4D34-8557-B938655B9EA4>
2. Centers for Disease and Prevention. Vaccine Effectiveness: How Well Do the Flu Vaccines Work?: <https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm?web=1&wdLOR=c1F64E497-5C1D-4203-A968-1F123E7B1D40>
3. European Medicines Agency (EMA). 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>
4. European Medicines Agency (EMA). Comirnaty: <https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty>
5. Centers for Disease and Prevention. Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Moderna COVID-19 Vaccine: <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-vaccine.html>
6. European Medicines Agency (EMA). COVID-19 Vaccine AstraZeneca: <https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-astrazeneca>
7. Centers for Disease and Prevention. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7009e4.htm>
8. The BMJ. Covid-19: Where are we on vaccines and variants? <https://www.bmj.com/content/bmj/372/bmj.n597.full.pdf>
9. The BMJ. Covid-19: Pfizer BioNTech vaccine reduced cases by 94% in Israel, shows peer reviewed study: <https://www.bmj.com/content/372/bmj.n567>



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