

March 19th 2021

COVID-19 Vaccine AstraZeneca® safety update

The European Medicines Agency (EMA) has recommended the AstraZeneca COVID-19 vaccine as safe and effective, whose benefits outweigh the risks, following a review of potential side effects carried out this week.

The National Immunisation Advisory Committee (NIAC), which is the expert group that advises on vaccination in Ireland, has recommended that vaccination with COVID-19 vaccine AstraZeneca should recommence. The HSE will now resume using the AstraZeneca vaccine within our ongoing COVID-19 vaccination programme. Hospitals, CHOs, service providers and clinicians will be supporting colleagues and patients who will now be invited for their vaccine.

Background:

- COVID-19 is a serious disease which has caused significant illness and death across the world including Ireland. COVID-19 vaccines have been developed and authorised for use after rigorous testing and have a favourable safety profile.
- More than 129,000 doses of COVID-19 Vaccine AstraZeneca® have been given to people in Ireland so far, mainly in frontline healthcare workers, and we can already see the significant reduction in cases of COVID-19 disease in this group since the vaccine programme began.
- On 14th March, NIAC recommended a temporary pause of in the use of COVID-19 Vaccine AstraZeneca®.
- This was because there had been a small number of very rare cases of blood clots in people who had received the vaccine in other European countries. These very rare blood clots were associated with low levels of blood platelets (platelets help blood to clot), with or without bleeding, including rare cases of clots in the vessels draining blood from the brain (CVST- cerebral venous sinus thrombosis).
- While the EMA investigated this, NIAC recommended pausing the use of the vaccine in Ireland pending the outcome.
- On 18th March, the EMA safety committee reported on the results of their investigation.
- NIAC reviewed this information from the EMA and on 19th March recommended that vaccination with COVID-19 Vaccine AstraZeneca® should recommence.
- THE HSE will resume administering the AstraZeneca vaccine tomorrow (Saturday 20th).

What has the EMA recommended?

The EMA safety committee carried out a comprehensive review of these rare cases of blood clots. Read the EMA statement here: <https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots>

This review found that:

- the benefits of the vaccine in combating the still widespread threat of COVID-19 (which itself results in clotting problems and may be fatal) continue to outweigh the risk of side effects;
- the vaccine is not associated with an increase in the overall risk of blood clots (thromboembolic events) in those who receive it;
- there is no evidence of a problem related to specific batches of the vaccine or to particular manufacturing sites;

- however, the vaccine may be associated with very rare cases of blood clots associated with thrombocytopenia, i.e. low levels of blood platelets (platelets help the blood to clot with or without bleeding, including rare cases of clots in the vessels draining blood from the brain (cerebral venous sinus thrombosis CVST).
- people being offered this vaccine should be given updated patient information, provided by the HSE, on what to be aware of in relation to these very rare events

What new information is available to allow the programme to restart?

Around 20 million people in the UK and in the European Economic Area (EEA) had received the COVID-19 Vaccine AstraZeneca® as of March 16th and EMA reviewed 7 cases of unusual blood clots in multiple blood vessels (called disseminated intravascular coagulation, DIC) and 18 cases of blood clots in the veins of the brain called CVST.

Overall the number of blood clots reported after vaccination, both in studies before the vaccine was available and in the reports after rollout of vaccination programmes, was lower than that expected in the general population.

This allows the EMA safety committee to confirm that there is no increase in overall risk of blood clots as a result of the COVID-19 Vaccine AstraZeneca®.

There have been very rare cases reported of unusual blood clots accompanied by low levels of blood platelets (platelets help the blood to clot) after vaccination. The reported cases were almost all in women under 55 years of age. The reason why cases happened in women under 55 years isn't known, but it may be because most of the people given the vaccine to date are healthcare workers, who are often younger women.

The number of these very rare reported events exceeds those expected, and a link to the vaccine cannot be confirmed or excluded. However, since the events are so rare, and it is difficult to establish baseline incidence since severe COVID-19 may lead to hospitalisation with clotting complications - the strength of any association is uncertain.

The EMA and the NIAC have concluded that because COVID-19 can be so serious and is so widespread, the benefits of the vaccine in preventing it outweigh the risks of side effects, including the extremely small possibility of these very rare unusual blood clots.

However, the EMA has updated the product documentation with information on cases of DIC and CVST that have occurred and the HSE is updating our patient information in relation to this vaccine. The EMA are continuing to review and monitor the vaccine and if new information becomes available, the HSE will update all our colleagues, partners and information channels.

It is important for both vaccinators and people who receive the vaccine to be aware of all the possible common, rate and very rare potential side effects of the vaccine. This includes being aware of the symptoms and signs of blood clots and to seek urgent medical attention if they experience them.

Questions and Answers

What should healthcare workers advise people due to receive COVID-19 Vaccine AstraZeneca® vaccine?

People being invited for vaccination are at high risk of COVID-19 disease and so we would advise that they attend their appointment to receive this vaccine as soon as it is offered to them. The European Medicines Agency and NIAC have concluded that the benefits of the vaccine outweigh the risks.

When will people be invited for their vaccine?

The groups who were affected by the pause in using this vaccine are Group 2 - frontline healthcare workers, and Group 4 – people who have conditions that put them at very high risk if they get COVID-19. Our services are now working to reschedule vaccination clinics for these groups, and will be in touch with colleague, or patients, to organise those appointments.

It is expected that vaccination with the AstraZeneca vaccine will recommence from Saturday March 20th in some hospitals.

Within Group 4, work has continued this week to identify people who are due to be invited for vaccines. The HSE and the wider health sector is working to invite people for vaccines, primarily through our hospital services, and our wider disability and mental health sector. We may also seek to contact people through their GPs, and through public information and advertising.

For now, we ask people in this group to not take any action. You don't need to ring your GP or hospital. The HSE or your healthcare team will be in touch with you when your vaccine is available.

What should I do if I am invited to receive COVID-19 Vaccine AstraZeneca® vaccine in the next few days?

We would advise that you attend your appointment to receive this vaccine as soon as it is offered to you. Anyone being invited for vaccination is at high risk of COVID-19 disease because they are a healthcare worker or live in a residential setting or are at high risk or serious illness and hospitalisation if they get COVID-19.

The European Medicines Agency (EMA) and NIAC have concluded that the benefits of the vaccine continue to outweigh the risks of side effects, including the extremely small possibility of developing unusual blood clots.

Where can I get more information before I attend my appointment?

Updated information for patients is available on the HSE website:

The statement from NIAC can be found at: <https://www.rcpi.ie/news/releases/the-national-immunisation-advisory-committee-niac-is-recommending-resumption-of-the-covid-19-vaccine-astrazeneca/>

Read the Patient Information leaflet: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-epar-product-information_en.pdf

Read the HSE Information leaflet: www.hse.ie/covid19vaccineresources

What are the symptoms people should watch out for that may mean a blood clot?

Please seek prompt medical assistance and mention your recent vaccination if you get any of the following symptoms:

- breathlessness
- pain in the chest or stomach
- swelling or coldness in an arm or leg
- severe or worsening headache (particularly 3 or more days after vaccination)
- blurred vision
- persistent bleeding under the skin where there was no injury
- multiple small bruises, reddish or purplish spots, or blood blisters under the skin,

The very rare blood clots were usually reported within 14 days of getting the COVID-19 Vaccine AstraZeneca®. You should watch out for these symptoms in the weeks after your vaccination.

What are the common side effects or symptoms people may get after receiving COVID-19 Vaccine AstraZeneca® vaccine?

We know that side effects of COVID-19 Vaccine AstraZeneca® usually happen in the first couple of days after the vaccine, and go away after a few days

After the AstraZeneca COVID-19 vaccine, more than 1 in 10 people may experience:

- feeling tired
- tenderness, bruising, pain, redness or itching in the arm where they had the vaccine injection
- headache
- muscle pain
- joint pain
- nausea, diarrhoea or vomiting
- fever (temperature of 38 degrees Celsius or above)

More than one in 100 people may have redness or swelling where they had the injection.

It is common to develop a fever (temperature of 38 degrees Celsius or above) after any vaccination. This usually happens within 2 days (48 hours) of getting the vaccine. It usually goes away within 2 days.

If you feel uncomfortable, take paracetamol or ibuprofen following the instructions on the box or leaflet.

Is there anyone who should not get the COVID-19 Vaccine AstraZeneca® vaccine?

There has been no change to the advice about who can get the COVID-19 Vaccine AstraZeneca®. The only people who should not receive the vaccine are those who have had anaphylaxis (serious allergic reaction) following a previous dose of the vaccine or any of its ingredients (including polysorbate 80).

People are advised to delay the vaccine if they are sick with a fever (temperature of 38 degrees Celsius or above). You should also delay vaccination if you have received another vaccine within the last 14 days or if you have had COVID-19 disease within the past 4 weeks.

What if I recently had a blood clot or I am on blood thinning treatments?

You can still have the COVID-19 Vaccine AstraZeneca® if you have recently had a blood clot or are on blood thinning treatments. There is no reason to delay vaccination. Like everyone who gets the vaccine, you should be aware of the symptoms to look out for.

What if I have a condition or I am on a treatment that may make me more likely to get a blood clot?

You can still have the COVID-19 Vaccine AstraZeneca®. There is no reason to delay vaccination. Like everyone who gets the vaccine, you should be aware of the symptoms to look out for.



Can pregnant women receive COVID-19 vaccine AstraZeneca?

Yes, pregnant women can receive COVID-19 vaccine AstraZeneca. There is no reason to delay vaccination. Like everyone who gets the vaccine, they should be aware of the symptoms to look out for as listed above. Recommendations of the NIAC should be followed in relation to vaccination in pregnancy.

What if people are taking the contraceptive pill, the contraceptive patch or the contraceptive ring (Nuvaring)?

You can still have the COVID-19 Vaccine AstraZeneca®. There is no reason to delay vaccination. Like everyone who gets the vaccine, you should be aware of the symptoms to look out for as listed above.

What if there is a history of blood clots in the family?

You can still have the COVID-19 Vaccine AstraZeneca®. There is no reason to delay vaccination. Like everyone who gets the vaccine, you should be aware of the symptoms to look out for.

Can people choose to get a different vaccine instead of the COVID-19 Vaccine AstraZeneca®?

At this time, supplies of the vaccines are limited so it is not possible to offer people a choice of COVID-19 vaccine. We recommend that people accept the vaccine that is offered to you to ensure you can be protected from COVID-19 as early as possible.

What about second doses of COVID-19 Vaccine AstraZeneca® vaccine?

People should get their second dose of COVID-19 Vaccine AstraZeneca® 12 weeks after your first dose. There are no appointments scheduled yet for second doses. You will be contacted for an appointment for your second dose. We recommend that you receive your second dose of vaccine when this is offered to you.

What should healthcare workers do if they suspect a patient is experiencing a thromboembolism in the weeks after COVID-19 Vaccine AstraZeneca®?

Healthcare professionals should seek early expert advice from the National Coagulation Centre about the specialised testing and treatment options for patients presenting with thromboembolic events that are associated with thrombocytopenia, (including Disseminated Intravascular Coagulation (DIC) or Cerebral venous sinus thrombosis (CVST)) occurring within weeks following vaccination with COVID-19 Vaccine AstraZeneca®

Should healthcare workers advise people to take aspirin before or after vaccination?

No, these are very rare blood clotting conditions and aspirin would not have a beneficial effect. People should be advised that they do not need to start aspirin treatment before or after vaccination.

Patients should continue to take all prescribed medication unless advised by their medical practitioner.