



Welcome to Bulletin 12 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

Bulletins will be published every week or more frequently, if required.

Update on the use of COVID-19 vaccines in pregnancy

The National Immunisation Advisory Committee has updated its guidelines on COVID-19 vaccines.

The gestational period when COVID-19 vaccines can be given in pregnancy has been extended to 36 weeks. Therefore where the risk/benefit for vaccination in pregnancy is favourable, the two dose schedule should be given between 14 and 36 completed weeks of gestation.

The 12 week interval between the two vaccine doses should be used where possible for COVID-19 Vaccine AstraZeneca® but the minimum interval can be used to complete the course.

e.g. a pregnant woman, who has her first dose of COVID-19 Vaccine AstraZeneca® at 32 weeks gestation, can be given her second dose at 36 weeks to complete the course.

Clinical guidance for vaccinators has been updated. Training on HSELand, medicines protocols and other supporting documents are being updated to reflect these changes.

Frequently asked questions on COVID-19 vaccine AstraZeneca®

We have developed frequently asked questions on COVID-19 Vaccine AstraZeneca®

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Have the contraindications and precautions to COVID-19 Vaccine AstraZeneca® changed?

No. The contraindications and precautions to COVID-19 vaccine AstraZeneca® have not changed.

The only contraindication to COVID-19 Vaccine AstraZeneca® is anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polysorbate 80).

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





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What if I a person had a blood clot in the past or is on blood thinning treatments?

They can still have 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 of thromboembolism or thrombocytopenia.

What if a person has a medical condition or is on treatment that may make them more likely to get a blood clot?

They can still have 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 in relation to thromboembolic events and thrombocytopenia.

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. Recommendations of the National Immunisation Advisory Committee should be followed in relation to vaccination in pregnancy.

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

People who have a history of blood clots in the family can still have 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.

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Allergies and COVID-19 vaccines

NIAC recommendations regarding contraindications and precaution to COVID-19 vaccines should be followed.

Contraindications

Each COVID-19 vaccine is contraindicated in people with a history of anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents. Constituents for mRNA vaccines include polyethylene glycol (PEG), and for COVID-19 Vaccine AstraZeneca® include Polysorbate 80.

Advice from a relevant specialist should be sought for a person with a history of an immediate systemic allergic reaction to any other vaccine, injectable therapy or, in the case of mRNA vaccines, polysorbate 80 (because of the cross reactivity with PEG). The risks should be weighed against the benefits of vaccination. They should be observed for 30 minutes after vaccination.

Regarding post-vaccine observation, the following is advised:

- Those with no history of anaphylaxis from any cause: 15 minutes
- Those with a history of anaphylaxis from any cause: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

NIAC does not recommend vaccination in a hospital setting for people with a history of allergies.

As stated above, advice from a relevant specialist should be sought for a person with a history of an immediate systemic allergic reaction to any other vaccine or injectable therapy.

For more information: the National Immunisation Advisory Committee (NIAC) together with the Irish Association of Allergy and Immunology (IAAI) have produced a Frequently Asked Questions (FAQ) document about COVID-19 vaccines for people with pre-existing allergic conditions.

Read More Here









Public Health England report of vaccine effectiveness

Public Health England has published a report of COVID-19 vaccine effectiveness.

The report includes data on vaccine effectiveness in preventing hospitalisations and severe disease in individuals aged 80+ who had received one dose of Comirnaty® Pfizer/BioNTech or COVID-19 Vaccine AstraZeneca®. One dose of either vaccine had vaccine effectiveness against hospitalisation of approximately 80%.

The study also reported on the effects from a single dose of Comirnaty® Pfizer/BioNTech on the risk of mortality in symptomatic cases of COVID-19 aged 80 and older who had been vaccinated. This risk of death was reduced by 54%. Combined with the reduced risk of becoming a case, this is consistent with a vaccine effectiveness against mortality of approximately 85%.

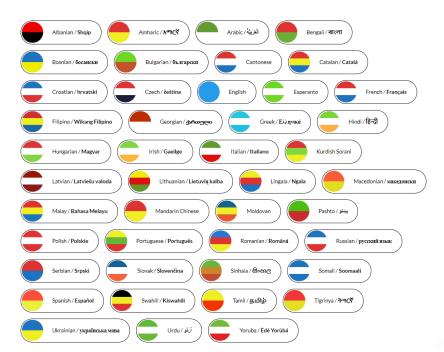
Read It Here

Materials in other languages

Translate Ireland in conjunction with our office; HSE Communications and HSE Social Inclusion have developed information videos to support the rollout of the COVID-19 vaccination programme in 36 languages.

We encourage you to use these and share them to support your patients and colleagues.

Visit https://translateireland.ie/.







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HPRA Update

The HPRA have published their drug safety newsletter on the conclusions of EMA review of thromboembolic events following vaccination with COVID-19 Vaccine AstraZeneca®. Key findings of this review include that:

- The benefits of the COVID-19 Vaccine Astra Zeneca® still outweigh any possible risks and the vaccine is not associated with an increased overall risk of developing blood clots in those who receive it.
- Rare cases of thrombosis and thrombocytopenia (low platelet count), some presenting as mesenteric vein or cerebral vein/cerebral venous sinus thrombosis (CVST), have been reported in persons who had recently received COVID-19 Vaccine AstraZeneca®, mostly occurring within 14 days after vaccination.
- The number of these particular reported events exceeded what was expected given the age and gender of the patients involved, and although not confirmed, the COVID-19 Vaccine AstraZeneca® cannot be excluded as the cause of these events.
- The benefit-risk balance of the medicine remains positive however, healthcare professionals should be alert to possible cases of thromboembolism, Disseminated Intravascular Coagulation (DIC) or CVST occurring in vaccinated individuals and advise recipients as to the symptoms and signs that require immediate medical attention.

Advice to healthcare professionals

- Healthcare professionals (HCPs) should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia following vaccination with COVID-19 Vaccine AstraZeneca®.
- HCPs should instruct those vaccinated to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches and blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

All reports of suspected adverse reactions should be reported to the HPRA via the available methods at www.hpra.ie/report.

Read More Here









COVID-19 Vaccination Training Programme

HSeLanD will be temporarily unavailable from **23.00hrs Friday 26 March to the morning of Monday 29 March** to perform an essential upgrade to their infrastructure to ensure better uptime and the stability of HSeLanD.

CoVax System Update

The CoVax System is due to be updated on **Monday night 29th March**.

The updates will be

- A new Vaccination tab will appear on the client record to access immunisation records
- Client vaccinated by GPs will have their vaccination records viewable in COVAX late next week
- A Covax Training environment is being developed
- Release notes will be sent out before the upgrade

Website

Visit our website <u>www.immunisation.ie</u> regularly for the most up to date information to support vaccinators and health professionals responding to queries.

Our dedicated COVID-19 Vaccination section contains

- Information from the National Immunisation Advisory Committee
- Clinical guidelines
- COVID-19 vaccine studies
- IM Injection technique reminders
- Dedicated pages for the licensed COVID-19 vaccines

Visit Here

Do you have queries?

For questions about the COVID-19 Vaccination programme

- COVID-19 vaccine orders or deliveries to GPs, please email gpvaccines@hse.ie
- Health Professionals for your own COVID-19 vaccination appointments, please email <u>Covid19.support@hse.ie</u>
- Legal queries, potential challenges related to vaccination and obtaining a consent, please email lead.integratedcare@hse.ie and dervelagray@rcpi.ie
- For clinical queries and queries relating to cold chain maintenance or breakdown, please email <u>immunisation@hse.ie</u>

The National Immunisation Office is not involved in the allocation or delivery of COVID-19 Vaccines.



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