COVID-19 VACCINE BULLETIN 45

Welcome to Bulletin 45 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

Extension of booster vaccination programme to children and young people aged 12-15 years

The National Immunisation Advisory Committee has issued new recommendations extending booster vaccinations to children and young people aged 12-15 years. These recommendations have been accepted by the Department of Health.

NIAC recommendations **Read more here**

These new recommendations have not yet been operationalised by the HSE. Information for parents, changes to the I.T system, medicines protocol, clinical guidance, supporting materials and training are being prepared.

Summary of recommendations

Comirnaty® 30 micrograms booster vaccination is recommended for those aged 12-15 years:

a. with underlying conditions as listed in Table 5a.2, Chapter 5a COVID-19
b. living with a younger child with complex medical needs
c. living with a person who is immunocompromised

Comirnaty® 30 micrograms booster vaccination should be offered to all others aged 12-15 years for the following reasons:

a. the favourable benefit risk profile of the vaccine
b. waning immunity following the primary vaccine course
c. to reduce the risks of asymptomatic, symptomatic, and severe COVID-19, and their complications, e.g., MIS-C, long COVID
d. to minimise psychological, social and developmental impacts and to help normalise life for adolescents
e. to increase the likelihood of protection against future variants

Prior to administration of the booster dose, adolescents along with their parents/guardians, should be informed of the benefits, risks and uncertainties of the booster dose of Comirnaty® vaccine. The decision to accept, defer or decline vaccination should be respected.

Recommended interval

The booster dose of Comirnaty® 30 micrograms should be given to children aged 12-15 years six months or longer following completion of the primary Comirnaty® vaccine course. In exceptional circumstances, a minimum interval of five months can be used.
Children aged 12-15 who are immunocompromised at the time of primary vaccination, should receive the booster dose at least 3 months after the additional dose was given.

Booster vaccination after COVID-19 infection

Children aged 12-15 who have a breakthrough COVID-19 infection following a primary vaccination course should defer booster vaccination for at least six months following infection onset.

Advice for young people who turn 16 three months after their primary course

If a young person turns 16 three months after their primary course, they can receive the booster dose using the interval of 3 months or longer for people aged 16 years and older (rather than the interval of 6 months or longer for children aged 12-15). It is the age at the time of vaccination that determines the interval so the recommended interval in this case is at least three months.

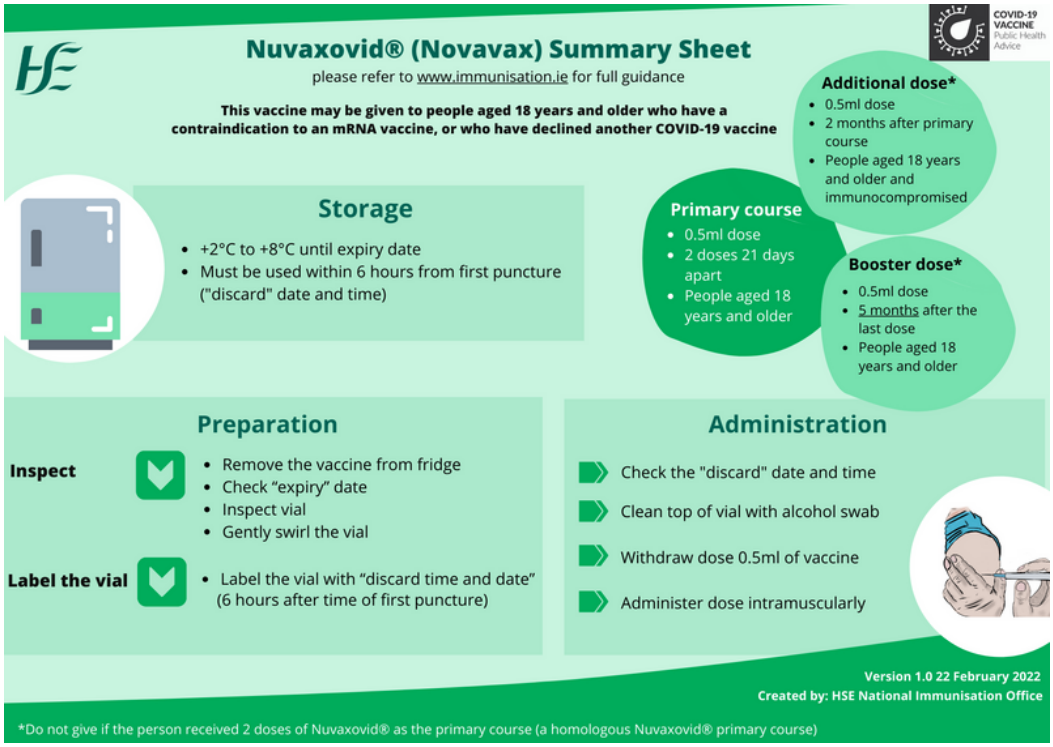
COVID-19 VACCINE BULLETIN 45

Nuvaxovid® (Novavax COVID-19 Vaccine)

The National Immunisation Advisory Committee has recommended **Nuvaxovid® (Novavax Covid-19 Vaccine)** for people with a contraindication/clinical precaution to mRNA vaccine or who have declined another authorised vaccine. These recommendations have been accepted by the Department of Health

NIAC recommendations **Read more here**

This vaccine is not yet available in Ireland. Plans are underway to include the vaccine into the vaccination programme when it becomes available.



See Summary Sheet here

The vaccine is a protein subunit vaccine

Protein based subunit vaccines present an antigen to the immune system using a specific, isolated protein of the pathogen, in this case the spike protein (other subunit vaccines are already in widespread use e.g. Hepatitis B vaccine).

The vaccine contains an 'adjuvant', a substance to help strengthen the immune responses to the vaccine. The adjuvant is called Matrix-M, and is derived from the soap bark tree Quillaja saponaria.

For full list of excipients **See SmPC here**

Vaccine efficacy

Vaccine efficacy from clinical trials in Mexico and the US to prevent the onset of COVID-19 was 90.4% from seven days after dose 2. A second UK study demonstrated efficacy of 89.7%.

COVID-19 VACCINE BULLETIN 45

Nuvaxovid® (Novavax COVID-19 Vaccine) (continued from page 2)

The vaccine is recommended for

- individuals aged 18 years and older with a contraindication to an mRNA vaccine

or

- Those aged 18 years and older who have declined another authorised COVID-19 vaccine

Dose, route and schedule

- Two 0.5 ml doses three weeks apart given IM in the deltoid muscle. The minimum interval of 17 days.

Presentation

The vaccine does not require dilution. It comes in a multi-dose vial with 10 doses per vial. If more than ten 0.5ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid vaccines.

Contraindications to Nuvaxovid®:

- A history of anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents including polysorbate 80.

Precautions to Nuvaxovid®:

- Acute severe febrile illness; defer until recovery.
- Advice from a relevant specialist should be sought for a person with a history of an immediate severe allergic reaction to multiple drug classes with no identified allergen, any other vaccine injected antibody preparation or medicine likely to contain polysorbate 80 or idiopathic anaphylaxis, and the risks should be weighed against the benefits of vaccination.

Pregnancy:

There is limited experience with use of the vaccine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, delivery or post-natal development.

- Administration may be considered when the benefits outweigh the potential risks to the mother or the foetus and when mRNA vaccines are contraindicated or declined.
- The two doses should be given 21 days apart at any stage in pregnancy.
- The pregnant women and a relevant health professional should engage in shared decision-making in advance of vaccination. A decision aid will be available from www.immunisation.ie

Breastfeeding

There is no known reason for vaccinees to avoid breastfeeding.

Co-administration

- Leave 14 days between Nuvaxovid® and any another vaccine except inactivated influenza vaccine which may be administered at the same time Novaxovid or at any interval.

COVID-19 VACCINE BULLETIN 45

Nuvaxovid® (Novavax COVID-19 Vaccine) (continued from page 2)

Booster or additional doses

Nuvaxovid® may be given as a booster or additional dose provided the individual has not already received Nuvaxovid as a 1st and 2nd dose (a homologous primary course).

If they received a different COVID-19 vaccine as the primary course, or received one dose of Nuvaxovid® as part of their primary course (a heterologous primary course), they may receive Nuvaxovid® as an additional or booster dose.

Recommended interval

Additional dose: 2 months after the primary course

Booster dose: **at least 5 months** after the primary course

Quick Reference Guide to COVID-19 Vaccines

This is a summary of information, the full clinical guidance and NIAC guidelines should be consulted at www.immunisation.ie

Vaccine	Comirnaty® Children's Formulation	Comirnaty® (Pfizer BioNTech)	Spikevax® (Moderna)	COVID-19 Vaccine Janssen®	Nuvaxovid® (Novavax)
Primary vaccination course (recommended for people aged 5 years and older)					
Age	**5-11 years**	**≥12 years**	**≥30 years**	**≥18 years**	**≥18 years**
Dose	**0.2mls**	0.3mls	0.5mls	0.5mls	0.5mls
Interval between 1st and 2nd dose	21 days	21-28 days	28 days	Not applicable	21 days
Interval since COVID-19 infection	At least 28 days	At least 28 days	At least 28 days	At least 28 days	At least 28 days
Additional dose for immunocompromised*					
Age	**5-11 years**	**≥12 years**	**≥30 years**	**≥18 years**	**≥18 years*** **
Dose	0.2mls	0.3mls	0.5mls	0.5mls	0.5mls
Interval since last dose	**28 days**	2 months	2 months	2 months	2 months
Interval since COVID-19 infection	**At least 3 months**	At least 3 months	At least 3 months	At least 3 months	At least 3 months
Booster dose**					
Age	**5-11 years**	**≥12 years**	**≥30 years**	**≥18 years**	**≥18 years*** **
Dose	**Not recommended**	0.3mls	0.25mls	0.5mls	0.5mls
Interval since last dose	**Not recommended**	**Age 12-15 years:** • at least **6 months** • **If immunocompromised:** at least **3 months** **Age ≥16 years:** at least **3 months**	At least 3 months	At least 3 months	At least **5 months**
Interval since COVID-19 infection	**Not recommended**	**Age 12-15 years (including immunocompromised):** at least **6 months** **Age ≥16 years:** at least **3 months**	At least 3 months	At least 3 months	At least 3 months

*An additional dose is recommended for immunocompromised people aged 5 years and older
** A booster dose is recommended for people aged 12 years and older
***Do not give if the person received Nuvaxovid® as a 1st and 2nd dose (homologous Nuvaxovid® primary course).

Version 18.0
24/02/2022

See Reference Guide here

COVID-19 VACCINE BULLETIN 45

Changes to recommendations regarding vaccination of children aged 5-11 years

If an 11 year old child received a 1st dose of Comirnaty® 10 micrograms/dose and turns 12 before their second dose, which vaccine should they receive as a second dose?

Previously NIAC advised that the dose was determined by the age of the child at the time of the first vaccine. NIAC has now advised that the dose is determined by the age of the child at the time of vaccination. Therefore: an 11 year old child who receives the first dose of 10 micrograms Comirnaty® (orange cap) and who is 12 years of age at the time of their second dose, should receive a dose of 30 micrograms Comirnaty® (purple cap).
This should be given after an interval of 21 days.

Frequently asked questions

One of my patients has become immunocompromised since receiving the booster dose. Does they need an additional dose now?

Individuals with immune-compromise **at the time of primary COVID-19 vaccination** may have a sub-optimal response to the vaccine. They are recommended an additional dose to enhance their response to the primary vaccination course. **It is person's condition at the time that they receive the primary vaccination course** that determines whether or not they need an additional dose.

The immunocompromising conditions associated with a suboptimal response to the primary vaccination course are shaded in blue in **Table 5a.2 of Immunisation Guidelines:**

Read more here

People who are at risk of severe COVID-19 disease, but do not have immunocompromise associated with a poor immune response at the time of vaccination, do not need an additional dose (e.g. diabetes, heart failure and conditions shaded in white in Table 5a.2). They are considered to develop an adequate immune response to the primary vaccination course. They need a booster dose after the primary vaccination course.

Covax updates

Sprint 18a goes live on 1st March 2022

- New medical assessment form for Nuvaxovid® (Novavax) COVID-19 vaccine on COVAX
- 3 new courses for Nuvaxovid® (Novavax)
- New Nuvaxovid® (Novavax) eligibility question for an Additional Dose/Booster - Novavax eligibility question for an Additional Dose/Booster

Vaccine Schedule Name
Novavax 21-Day
Novavax Booster - 152 days
Novavax Additional Dose - 60 days

- Medical assessment form for Nuvaxovid® (Novavax) has 7 questions and 9 for the additional and booster doses

COVID-19 VACCINE BULLETIN 45

Covax updates
(continued from page 5)

New questions for Nuvaxovid®

1. Reason for vaccination

*** Do you have a contraindication to mRNA vaccines (Pfizer/BioNTech (Comirnaty®) or Moderna (Spikevax®)) or have made an informed choice not to get an mRNA vaccine?**

- ◯ Yes
- ◯ No

If yes, go to the next question.
If no, you cannot get this vaccine. mRNA vaccines remain the preferred choice for the primary and booster vaccines. Please book an appointment for an mRNA vaccine if you have no contraindications.

If yes, eligible.

2. Two new allergy questions relating to polysorbate allergy
3. Any other vaccines other than flu in the last 14 days or in next 14 days
4. Pregnancy
5. Question if had a primary course of Nuvaxovid®

Old questions

1. Bleeding question
2. Post Covid-19 infection delaying vaccination
3. Question regarding an additional dose or booster in the last 3 months
4. Mastocytosis question

Note: For all vaccines this question has changes to

*** Have you ever had Mastocytosis (rare condition caused by an excess number of mast cells gathering in the body's tissues)?**

- ◯ Yes
- ◯ No

If yes, you can still get the vaccine, BUT, you should be observed for 30 minutes after you are vaccinated.

Booster dose for 12-15 years olds

- To administer use current Pfizer Booster - 90 days
- There are no warning on system for intervals on COVAX fro the boosters for 12-15 year olds.
- The interval for boosters is 6 months with a minimum of 5 months or 3 months for immunocompromised groups.
- Vaccinators must check this before administering the Booster to 12-15 year olds.
- Sprint 19 will bring a dedicated booster for 12-15 years with interval, offsets and warning message if given too soon.

COVID-19 VACCINE BULLETIN 45

Website

Visit our website **www.immunisation.ie** 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

HSeLanD COVID-19 Vaccination Training Programme

You can access updates to the National Immunisation Office COVID-19 Vaccination Training Programme for

- Children 5 to 11
- Pfizer,
- Moderna, and
- Janssen vaccine

through your HSeLanD account.

We would encourage you to log in and complete the updated content in each programme to refresh your knowledge and ensure you are up to date with your COVID-19 Vaccination Training.

Visit HSeLanD

If you have any issues with the platform please contact HSeLand directly.

Contact HSeLanD

Do you have queries?

Clinical queries from healthcare professionals can be directed to our HSE email address.

Send your query

Should vaccines be exposed to temperatures outside of parameters please contact the National Immunisation Office pharmacists immediately. Contacts include:

- Mariangela Toma: mobile 087 7575679
- Cliona Kiersey: mobile 087 9915452
- Achal Gupta: mobile 087 4064810

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

Queries that are not clinical or technical cannot be answered by the National Immunisation Office

Read about the role of the National Immunisation Office in supporting the COVID-19 vaccination programme on our **website**.

Recommendations about COVID-19 vaccine are changing as more information becomes available so please visit our **website** for the most up to date information.