COVID-19 Vaccine Overview Ireland

CVSIG meeting Mar 2021

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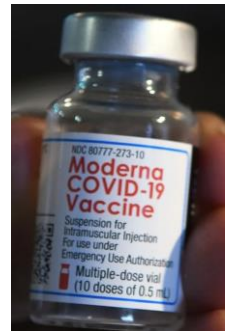
Irish Medication Safety Network

COVID19 vaccines conditional marketing authorisation by European Medicines Agency

1. Pfizer BioNTech (Comirnaty) - 21 Dec 2020 – preferred in those >70yrs in Ireland
Multidose vial (0.45 mL) contains 6 doses of 0.3 mL (30microg) COVID19 mRNA vaccine after dilution. Dosing: Two x 0.3mL doses - 28 days apart
Certain batches reliable to obtain 7 doses with low dead space syringes



2. Moderna – 6 Jan 2021 (*minor proportion of COVID19 vaccine supply to date)
Multidose vial (5mL) COVID19 mRNA vaccine which contains 10 doses of 0.5 mL
Dosing: Two x 0.5mL doses - 28 days apart

3. AstraZeneca - 29 Jan 2021 – for those under 70 yrs
Multidose vial (5mL) viral vector vaccine which contains 10 doses of 0.5 mL
Have been able to obtain up to 12 doses per vial
Dosing: Two x 0.5mL doses - 12 weeks apart

Registration via national vaccination system (COVAX)

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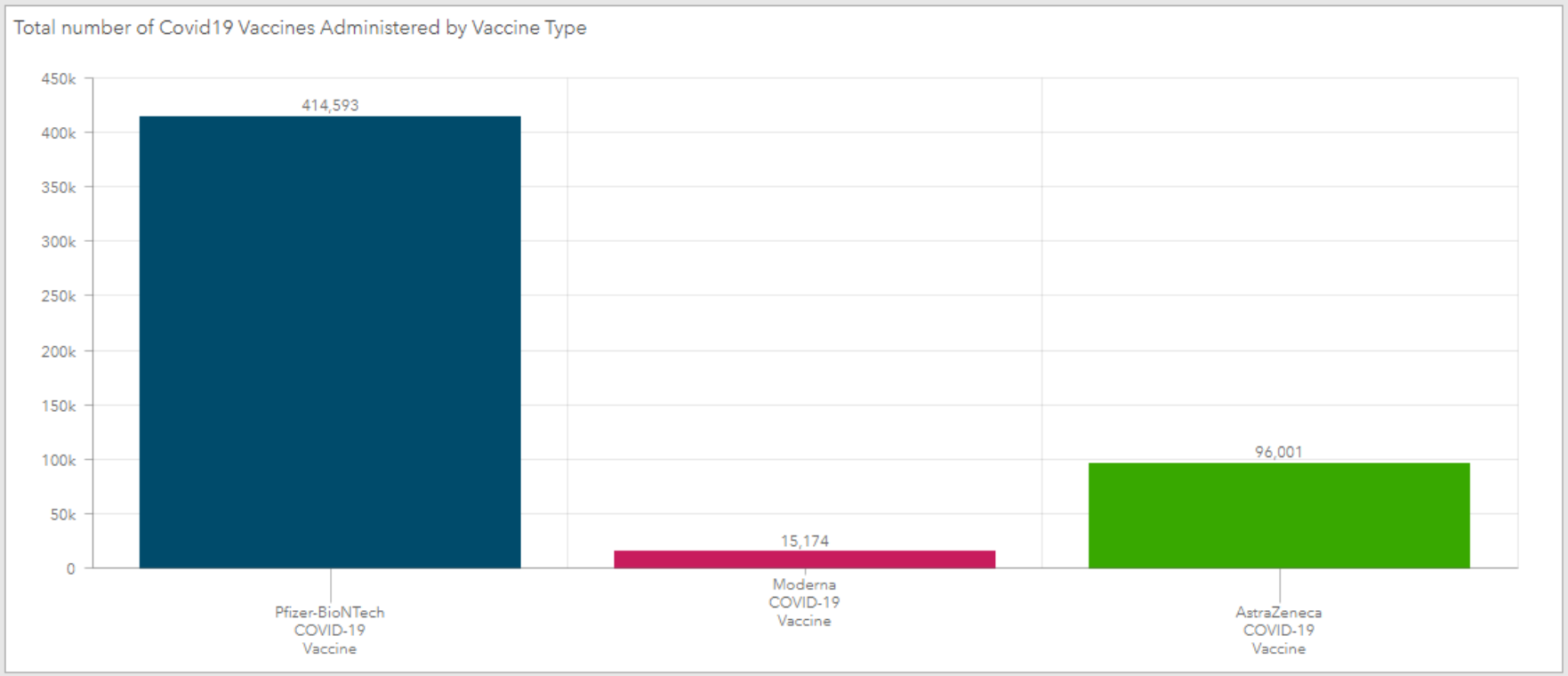
COVID-19 Vaccine Information fc | Polypharmacy: Manage Medicine | Ireland's COVID19 Data Hub - Va

covid19ireland-geohive.hub.arcgis.com/pages/vaccinations

COVID-19 Ireland | Vaccinations | ICU, Hospital & Testing | Detailed Profile of Cases | Detailed County & LEA Statistics | More

Total 1st Dose Vaccines Administered	Total 2nd Dose Vaccines Administered	Total Vaccines Administered
375,521	150,247	525,768



Provisional Vaccine Allocation Groups

gov.ie

From Department of Health
Published on 8 December 2020
Last updated on 26 February 2021

1. Adults aged ≥65 years who are residents of long-term care facilities
2. Frontline healthcare workers
3. People aged 70 and older
4. Aged 16-69 and at very high risk of severe COVID-19 disease
5. Aged 65-69 whose underlying condition puts them at a high risk of severe disease and death
6. People aged 65-69, other healthcare workers, and key vaccination programme workers
7. Aged 16-64 and at high risk of severe COVID-19 disease
8. Residents of long-term care facilities aged 18-64
9. Aged 18-64 years living working in crowded accommodation where self-isolation and social distancing is difficult to maintain
10. Key workers in essential jobs who cannot avoid a high risk of exposure to COVID-19
11. People essential to education and who face disease exposure
12. Aged 55-64 years
13. People in occupations important to the functioning of society
14. Aged 18-54 years who did not have access to the vaccine in prior phases
15. Children, adolescents up to 18 years and pregnant women (to be refined)

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Vaccine Roll out - First phase end Dec ‘20

- Frontline healthcare worker/Residential care residents >65yrs & residential care staff
- Pharmacy involvement high (but variable) from hospitals re dilution of Pfizer, vial reconciliation, process flow, and medicines information enquiries
- Administration of vaccine by Nursing (& Medical)
- Initially Pfizer BioNTech (minority Moderna) now AstraZeneca
- Vaccine dose preparation in most cases carried out at the point of administration
- Low Dead Volume Syringes enhance reliable yield

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Mass vaccination roll out Feb 21 onwards

- Over 70s priority group – starting with patients >85yrs
- GP Practices and mass vaccination centres country wide
- Pfizer BioNTech preferred vaccine
- Pharmacist role in vaccine stewardship
- Administration by Nursing (& Medical)
- Future vaccinators: Community Pharmacists in Pharmacy, Physios, Dentists, Optometrists

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Incidents/learning reported

- Teething issues re transport, storage, standards for cool boxes
- Communication re vaccine delivery and timing
- Leakage from vials on reconstitution
- Variability in vial yield
- Insufficient consumables
- Risk of blood borne disease transmission with multidose vials
- Planning for end of clinic doses/standby list
- Adverse drug reactions/Side Effects

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Side Effects Reported

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

mRNA vaccines (Comirnaty® and COVID-19 Vaccine Moderna®)

10% or more of suspected side effects reported:

- Dizziness, headache
- Muscle Pain, general pain
- Nausea
- Tiredness, chills, fever

1% to less than 10% of suspected side effects reported:

- Altered taste, cough, difficulty breathing
- Enlarged lymph nodes
- Insomnia,
- Increased heart rate/racing heart, blood pressure increase
- Injection site redness, injection site pain, injection site swelling
- Itchiness, rash, hives
- Joint pain, pain in limbs, chest pain, neck pain
- Numbness, tingling/pins and needles
- Vomiting, diarrhoea, abdominal pain
- Weakness, feeling unwell, feeling hot and/or cold, decreased appetite, fainting, sweating, flushing

COVID-19 Vaccine AstraZeneca®

10% or more of suspected side effects reported:

- Headache
- Muscle pain, pain in limbs
- Nausea
- Feeling unwell, fever

1% to less than 10% of suspected side effects reported:

- Altered taste, cough, difficulty breathing
- Dizziness, increased heart rate/racing heart, insomnia
- Enlarged lymph nodes
- Injection site pain, injection site redness
- Joint pain, muscle weakness/stiffness, back pain, migraine
- Vomiting, diarrhoea, abdominal discomfort/pain
- Numbness, tingling/pins and needles, tremor
- Weakness, tiredness, chills, feeling hot and/or cold, sweating, decreased appetite

Reports of interest:

- Allergic type reactions, Systemic events, Deaths post vaccination

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COVID-19 Vaccines, Overview of National Reporting Experience update 4 Mar 2021 via hpra.ie

Learning from Process

- Ensure new staff aware of processes in place and why
- Consumables & Low Dead Space Syringes availability
- Collation of medicines information resources
- Time out between clinic change of vaccines
  - 0.3mL dose Pfizer
  - 0.5mL Dose AstraZeneca
- Last man standing – plan for end of clinic to ensure zero waste – standby lists
- Logistics – locations, sequencing, vaccine choice

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Real time learning

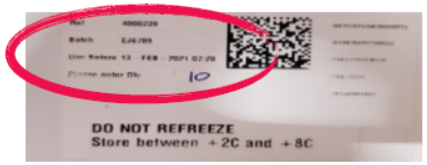
COVID-19 VACCINE BULLETIN 7

Welcome to the seventh bulletin 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.

What information regarding the shelf-life of the vaccine should be recorded in the IT system/vaccination record?

Comirnaty® (Pfizer/BioNTech)

- The batch number should be recorded
- The "use before" date and time should be recorded (see table below)
- The batch number and expiry date of the saline diluent should also be recorded



***"Use before"* date and time** **Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C**	USE BEFORE date and time = 120 hours from the time vials are removed by HSE National Cold Chain from ULT and stored at 2°C to 8°C (must be recorded on patient's notes). Before the 120 hours have passed, vials must be removed from fridge. They can be kept for up to 2 hours at room temperature in preparation for dilution. Within the 2 hours the vial must be diluted. DISCARD date and time = 6 hours from dilution (Must be written on the vial).

COVID-19 Vaccine Moderna®

- The batch number should be recorded
- The "use before" date should be recorded (see table below)

***"Use before"* date and time** **30 days from date and time of arrival of the vaccines to vaccination site/clinic and stored at +2°C and + 8°C.**	The vaccine is transported by the HSE National Cold Chain service to vaccination sites/clinics frozen at -25°C and -15°C. At vaccination sites/clinics the vaccine is stored at +2°C and +8°C and thawed. If thawed and stored between +2°C and +8°C, the unopened vaccine has a shelf life of 30 days. This "use before" date and time is 30 days from date and time of delivery of vaccines by the NCCS van driver. The recipient must record the "use before" on the vaccine box. The vials must be discarded when the "use before" date and time has been reached.

HSE COVID19 vaccine guidance for HCP
https://bit.ly/3eqjMmb

Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions

Published January 2021

Prepared by:

Irish Association of Allergy and Immunology

National Immunisation Advisory Committee (NIAC)

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

COVID-19 VACCINE Public Health Advice

Clinical Guidance for COVID-19 Vaccination

Version 10.0

04/03/2021

Questions and Answers for pregnant or breastfeeding women and their doctors about COVID-19 vaccination

information specific to:

- Comirnaty® - Pfizer/BioNTech
- COVID-19 Vaccine - Moderna
- COVID-19 Vaccine- Astra Zeneca

Updated February 2021

Prepared by:

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

Irish Medicines in Pregnancy Services THE ROTUNDA HOSPITAL DUBLIN

National Immunisation Advisory Committee (NIAC)

Endorsed by:

National Women & Infants Health Programme

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