🇮🇪 & 🇬🇧 COVID 🧵 🧵 🧵

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🧵 🧵 🧵 on COVID twitter.com/ThreadsIrish/s…

Aug. 31, 2021 · 2 min read

1. Are You Interested In Reading The Pfizer Comirnaty Leaflets I Was Given At The Walk-In Vaccination Centre

For the sake of completeness from yesterday's 🧵 I said I would post these. When I checked in I was handed these 3 leaflets.

New 🧵 1/18

🇮🇪 & 🇬🇧 COVID 🧵🧵🧵
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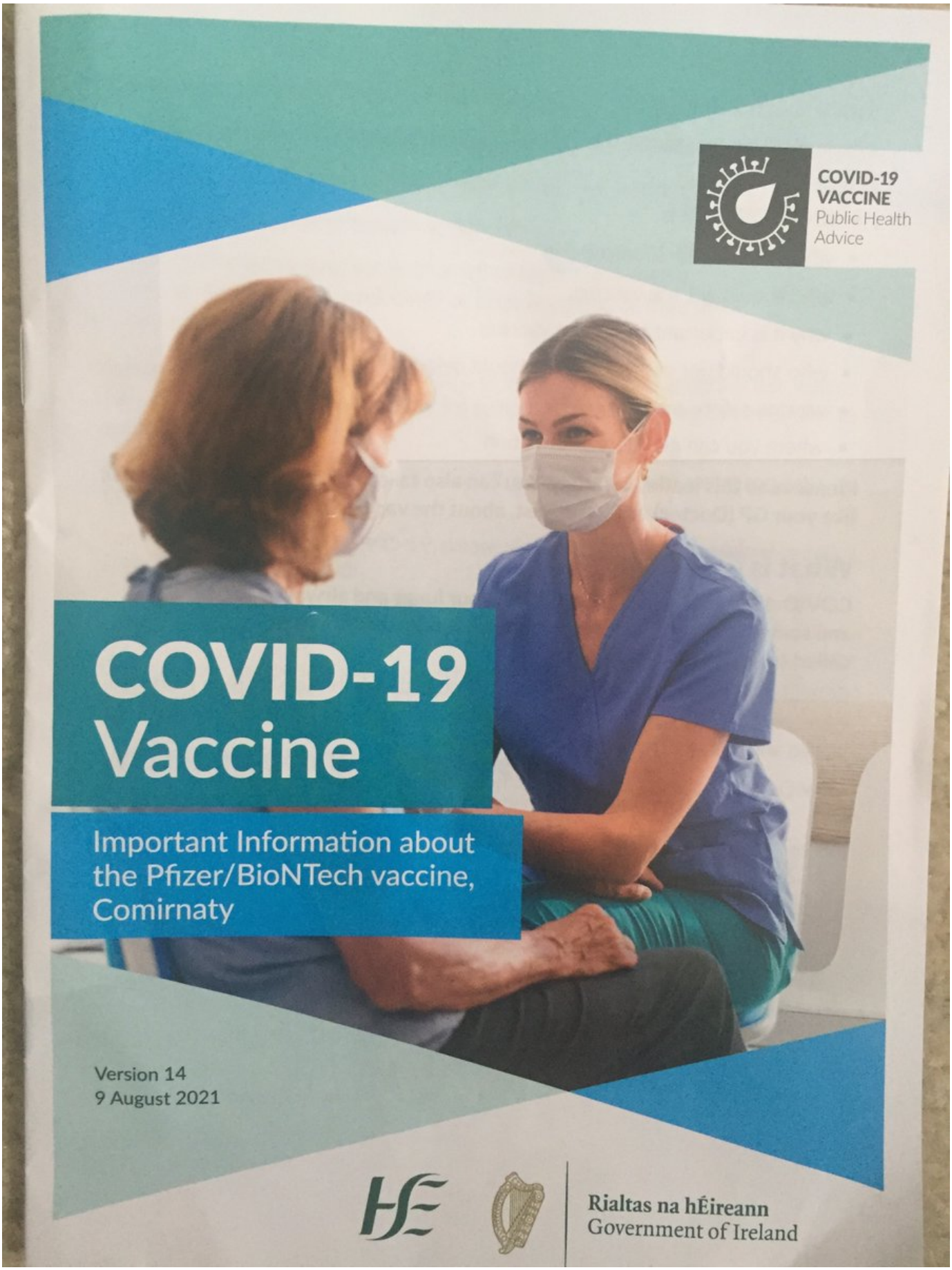
1. How My Visit Went To A Walk-In Vaccination Clinic

The purpose of this fact gathering exercise was to see how busy the walk-in clinic was and to ask the vaccinator some questions or legitimate concerns I had about the v. New🧵 1/25

10:19 AM · Aug 30, 2021



2. I know there has been a lot of discussion about the status of the v and whether it now has approval. I don't claim to be up to speed on that so I will leave that to people who are way more qualified than me to have that discussion in the comments.

3. Please remember that these leaflets are for the Irish market. Depending on where you are in the world they may be different as might the approval status of Comirnaty.

I'll just add a few things I noticed whilst having a quick glance over them

4. Comirnaty Package Leaflet 1 12/07/21

Point 1 "As Comirnaty does not contain the virus to produce immunity, it cannot give you Covid-19"

Point 2 "Comirnaty is not recommended for children under 12 years"

Myocarditis & Pericarditis mentioned

Package leaflet: Information for the user

Comirnaty™

concentrate for dispersion for injection

COVID-19 mRNA Vaccine (nucleoside modified)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Comirnaty is and what it is used for

Comirnaty is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus.

Comirnaty is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty does not contain the virus to produce immunity, it cannot give you COVID-19.

2 What you need to know before you receive Comirnaty

Comirnaty should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Comirnaty in the past.
- you have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported after vaccination with Comirnaty. The cases have primarily occurred within two weeks following vaccination, more often after the second vaccination, and more often occurred in younger men. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, the 2-dose vaccination course of Comirnaty may not fully protect all those who receive it and it is not known how long you will be protected.

Children

Comirnaty is not recommended for children under 12 years.

Other medicines and Comirnaty

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

Comirnaty contains potassium and sodium

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3 How Comirnaty is given

Comirnaty is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 2 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose to complete the vaccination course.

If you have any further questions on the use of Comirnaty, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all vaccines, Comirnaty can cause side effects, although not every-body gets them.

Very common: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain

5. Ingredients - What Comirnaty contains

• diarrhoea
• fever

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people
• injection site redness
• nausea
• vomiting

Uncommon side effects: may affect up to 1 in 100 people
• enlarged lymph nodes
• feeling unwell
• arm pain
• insomnia
• injection site itching
• allergic reactions such as rash or itching

Rare side effects: may affect up to 1 in 1,000 people
• temporary one sided facial drooping
• allergic reactions such as hives or swelling of the face

Not known (cannot be estimated from the available data)
• severe allergic reaction
• inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system and include batch/Lot number if available:

- Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Comirnaty

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C. Within the 6 months shelf-life unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C.

Store in the original package in order to protect from light.

Transfers of frozen vials stored at ultra-low temperature (< -60 °C)

- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 5 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- After vial trays are returned to frozen storage following temperature exposure up to 25 °C, they must remain in frozen storage for at least 2 hours before they can be removed again.

Transfers of frozen vials stored at -25 °C to -15 °C

- Closed-lid vial trays containing 195 vials removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 1 minute.

Once a vial is removed from the vial tray, it should be thawed for use.

After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once removed from freezer, the undiluted vaccine can be stored for up to 1 month at 2 °C to 8 °C. Within the 1-month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation. Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30 °C.

After dilution, store and transport the vaccine at 2 °C to 30 °C and use within 6 hours. Discard any unused vaccine.

Once removed from the freezer and diluted, the vials should be marked with the new discard date and time. Once thawed, the vaccine cannot be re-frozen.

Do not use this vaccine if you notice particulates in the dilution or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Comirnaty contains

• The active substance is COVID-19 mRNA Vaccine. After dilution, the vial contains 6 doses of 0.3 mL with 30 micrograms mRNA each. The other ingredients are:

- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
- 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
- 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium phosphate dihydrate
- sucrose
- water for injections

What Comirnaty looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a flip-off plastic cap with aluminium seal.

Pack size: 195 vials

Marketing Authorisation Holder

BioNTech Manufacturing GmbH

An der Goldgrube 12, 55131 Mainz, Germany

Phone: +49 6131 9084-0, Fax: +49 6131 9084-2121
service@biontech.de

Manufacturer

BioNTech Manufacturing GmbH, Kupferbergterrasse 17 - 19, 55116 Mainz, Germany

Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

• **Ireland:** Pfizer Healthcare Ireland, Tel: 1800 633 363 (toll free), +44 (0)1304 616161

This leaflet was last revised in 07/2021.

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine. The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Scan the code with a mobile device to get this information in different languages.

URL: www.comirnatyglobal.com

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This package leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

Administer Comirnaty intramuscularly after dilution as a course of 2 doses (0.3 mL each) 3 weeks apart.

Traceability

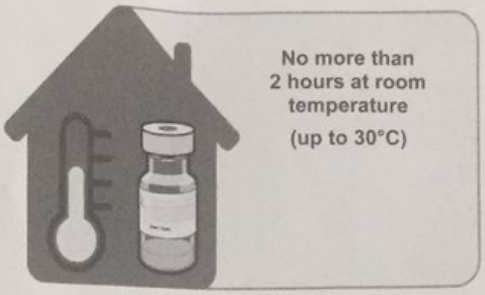
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions

- Comirnaty should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion

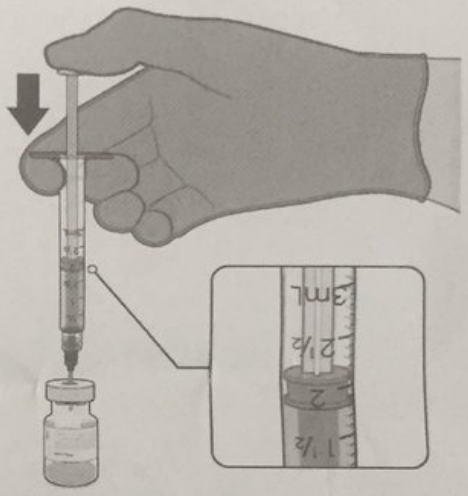
THAWING PRIOR TO DILUTION

- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2°C to 8°C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30°C for immediate use.
- The unopened vial can be stored for up to 1 month at 2 °C to 8 °C. Within the 1 month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation.
- Allow the thawed vial to come to room temperature and gently invert it 10 times prior dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.



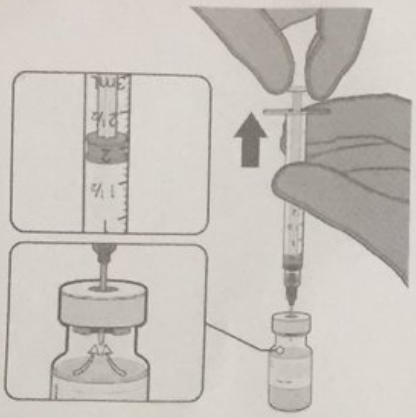
DILUTION

- The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.



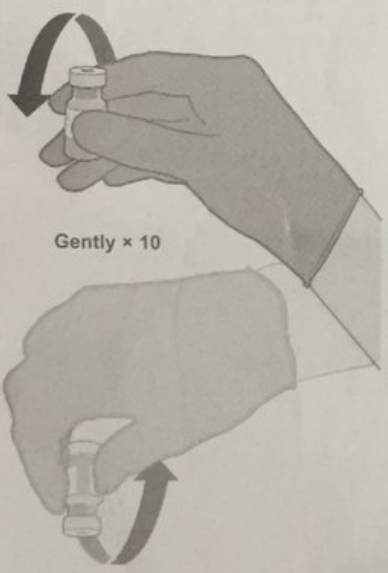
1.8 mL of 0.9% sodium chloride injection

- Equalise vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.

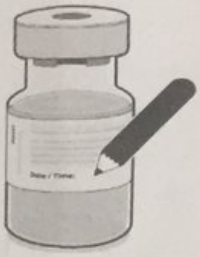


Pull back plunger to 1.8 mL to remove air from vial.

- Gently invert the diluted dispersion 10 times. Do not shake.



- The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
- The diluted vials should be marked with the new discard date and time.
- After dilution store at 2°C to 30°C and use within 6 hours, including any transportation time.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.



Record appropriate date and time.
Use within 6 hours after dilution

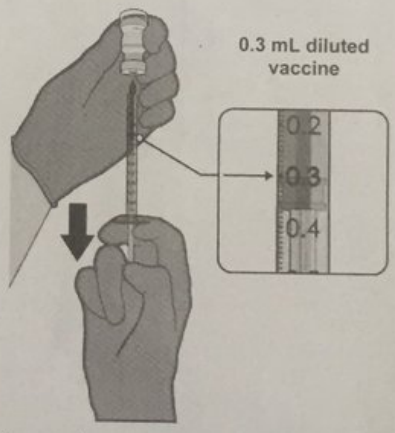
PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY

- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 6 hours after dilution.

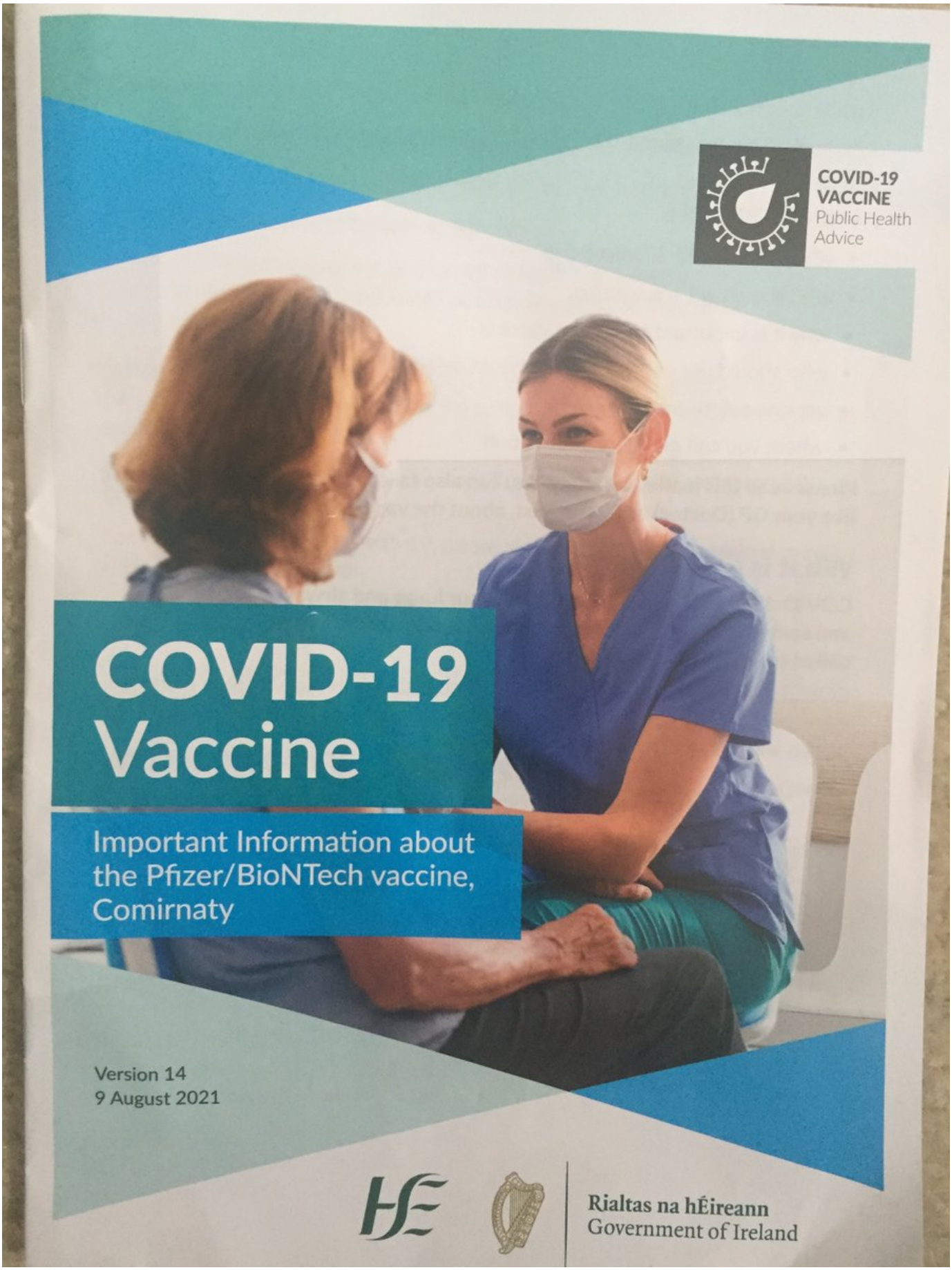


Disposal

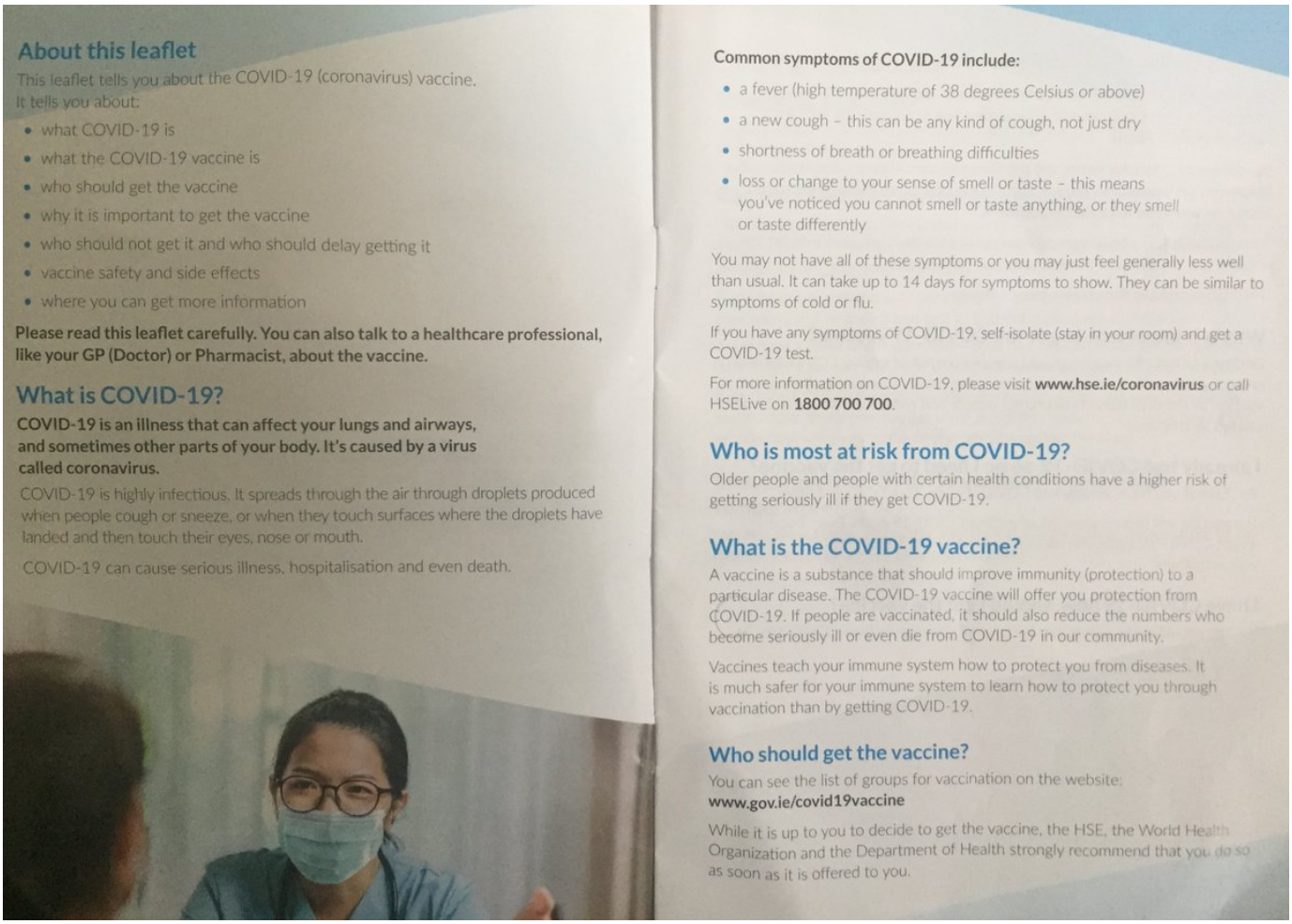
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Version: Comirnaty PIL Ireland 21_07 _12

8. Front Page COVID-19 Vaccine Leaflet 2
Version 14 9 August 2021



9. "It is much safer for your immune system to learn how to protect you through vaccination than by getting COVID-19"



About this leaflet

This leaflet tells you about the COVID-19 (coronavirus) vaccine.
It tells you about:

- what COVID-19 is
- what the COVID-19 vaccine is
- who should get the vaccine
- why it is important to get the vaccine
- who should not get it and who should delay getting it
- vaccine safety and side effects
- where you can get more information

Please read this leaflet carefully. You can also talk to a healthcare professional, like your GP (Doctor) or Pharmacist, about the vaccine.

What is COVID-19?

COVID-19 is an illness that can affect your lungs and airways, and sometimes other parts of your body. It's caused by a virus called coronavirus.

COVID-19 is highly infectious. It spreads through the air through droplets produced when people cough or sneeze, or when they touch surfaces where the droplets have landed and then touch their eyes, nose or mouth.

COVID-19 can cause serious illness, hospitalisation and even death.

Common symptoms of COVID-19 include:

- a fever (high temperature of 38 degrees Celsius or above)
- a new cough – this can be any kind of cough, not just dry
- shortness of breath or breathing difficulties
- loss or change to your sense of smell or taste – this means you've noticed you cannot smell or taste anything, or they smell or taste differently

You may not have all of these symptoms or you may just feel generally less well than usual. It can take up to 14 days for symptoms to show. They can be similar to symptoms of cold or flu.

If you have any symptoms of COVID-19, self-isolate (stay in your room) and get a COVID-19 test.

For more information on COVID-19, please visit **www.hse.ie/coronavirus** or call HSELive on **1800 700 700**.

Who is most at risk from COVID-19?

Older people and people with certain health conditions have a higher risk of getting seriously ill if they get COVID-19.

What is the COVID-19 vaccine?

A vaccine is a substance that should improve immunity (protection) to a particular disease. The COVID-19 vaccine will offer you protection from COVID-19. If people are vaccinated, it should also reduce the numbers who become seriously ill or even die from COVID-19 in our community.

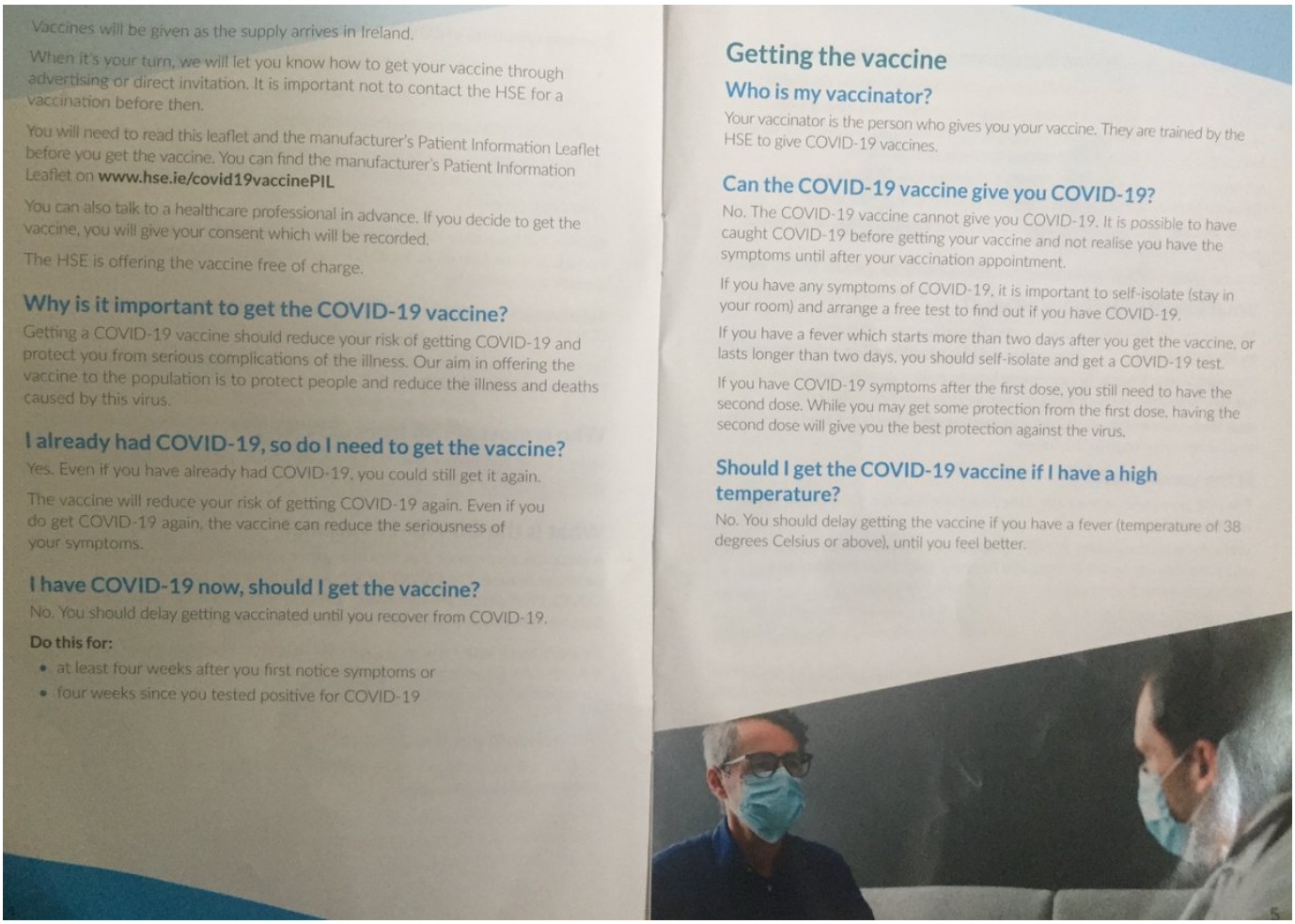
Vaccines teach your immune system how to protect you from diseases. It is much safer for your immune system to learn how to protect you through vaccination than by getting COVID-19.

Who should get the vaccine?

You can see the list of groups for vaccination on the website:
www.gov.ie/covid19vaccine

While it is up to you to decide to get the vaccine, the HSE, the World Health Organization and the Department of Health strongly recommend that you do so as soon as it is offered to you.

10. "The COVID-19 vaccine cannot give you COVID-19. It is possible to have caught COVID-19 before getting your vaccine and not realise you have the symptoms until after your vaccination appointment"



Vaccines will be given as the supply arrives in Ireland.

When it's your turn, we will let you know how to get your vaccine through advertising or direct invitation. It is important not to contact the HSE for a vaccination before then.

You will need to read this leaflet and the manufacturer's Patient Information Leaflet before you get the vaccine. You can find the manufacturer's Patient Information Leaflet on **www.hse.ie/covid19vaccinePIL**

You can also talk to a healthcare professional in advance. If you decide to get the vaccine, you will give your consent which will be recorded.

The HSE is offering the vaccine free of charge.

Why is it important to get the COVID-19 vaccine?

Getting a COVID-19 vaccine should reduce your risk of getting COVID-19 and protect you from serious complications of the illness. Our aim in offering the vaccine to the population is to protect people and reduce the illness and deaths caused by this virus.

I already had COVID-19, so do I need to get the vaccine?

Yes. Even if you have already had COVID-19, you could still get it again.

The vaccine will reduce your risk of getting COVID-19 again. Even if you do get COVID-19 again, the vaccine can reduce the seriousness of your symptoms.

I have COVID-19 now, should I get the vaccine?

No. You should delay getting vaccinated until you recover from COVID-19.

Do this for:

- at least four weeks after you first notice symptoms or
- four weeks since you tested positive for COVID-19

Getting the vaccine

Who is my vaccinator?

Your vaccinator is the person who gives you your vaccine. They are trained by the HSE to give COVID-19 vaccines.

Can the COVID-19 vaccine give you COVID-19?

No. The COVID-19 vaccine cannot give you COVID-19. It is possible to have caught COVID-19 before getting your vaccine and not realise you have the symptoms until after your vaccination appointment.

If you have any symptoms of COVID-19, it is important to self-isolate (stay in your room) and arrange a free test to find out if you have COVID-19.

If you have a fever which starts more than two days after you get the vaccine, or lasts longer than two days, you should self-isolate and get a COVID-19 test.

If you have COVID-19 symptoms after the first dose, you still need to have the second dose. While you may get some protection from the first dose, having the second dose will give you the best protection against the virus.

Should I get the COVID-19 vaccine if I have a high temperature?

No. You should delay getting the vaccine if you have a fever (temperature of 38 degrees Celsius or above), until you feel better.

11. "In order to be approved for use, the COVID-19 vaccine went through all the clinical trials and safety checks all other licensed medicines go through, following international standards of safety"

Should I get the vaccine if pregnant or breastfeeding?

There's no evidence that the COVID-19 vaccine is unsafe if you're pregnant.

COVID-19 vaccines were not tested on pregnant women in the clinical trials. However, over 100,000 pregnant women in the US have had a COVID-19 vaccine. No safety concerns have been identified for them or their babies.

It's recommended you get your COVID-19 vaccine when it's offered to you. Being vaccinated will reduce the chance of you becoming very unwell.

If you are pregnant, you should talk to your Obstetrician or GP (Doctor) about getting the COVID-19 vaccine.

You can get the COVID-19 vaccine if you are breastfeeding.

What vaccine am I being offered?

The vaccine we are offering you is called Comirnaty, manufactured by Pfizer/BioNTech.

This mRNA vaccine teaches your body how to make a protein that will trigger an immune response, without using the live virus that causes COVID-19.

Your body then makes antibodies that help fight the infection if the COVID-19 virus enters your body in the future.

Is the vaccine safe?

The HSE only uses vaccines when they meet the required standards of safety and effectiveness.

While the work to develop COVID-19 vaccines has moved much faster than usual, the vaccine we are offering you has gone through all the usual steps needed to develop and approve a safe and effective vaccine.

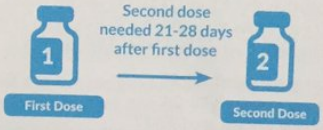
In order to be approved for use, the COVID-19 vaccine went through all the clinical trials and safety checks all other licensed medicines go through, following international standards of safety.

The vaccine we are offering you is called Comirnaty, manufactured by Pfizer/BioNTech. It has:

- ✔ been tested with thousands of people as part of clinical trials
- ✔ met strict standards of safety, quality and effectiveness, and been approved and licensed by regulators. For Ireland, the regulator is the European Medicines Agency (EMA) – visit **www.ema.europa.eu** for more information

How is the COVID-19 vaccine given?

The COVID-19 vaccine is given as an injection into your upper arm. It will only take a few minutes.



How many doses of the COVID-19 vaccine will I need?

You will need two doses of the COVID-19 vaccine to get the best protection. You need to get the second dose 21-28 days after the first dose.

What are the side effects of the vaccine?

Like all medicines, vaccines can cause side effects. Most of these are mild to moderate, short-term, and not everyone gets them.

More than one in 10 people may experience:

- feeling tired
- tenderness or swelling in your arm where you have had the vaccine injection
- headache
- muscle pain
- joint pain
- diarrhoea
- fever (temperature of 38 degrees Celsius or above)

More than 1 in 100 people may develop nausea, vomiting or redness where the vaccine was given.

More than 1 in 1,000 people will develop itchiness where the vaccine was given, generalised itchiness, a rash, swelling of the lymph glands or sleeplessness.

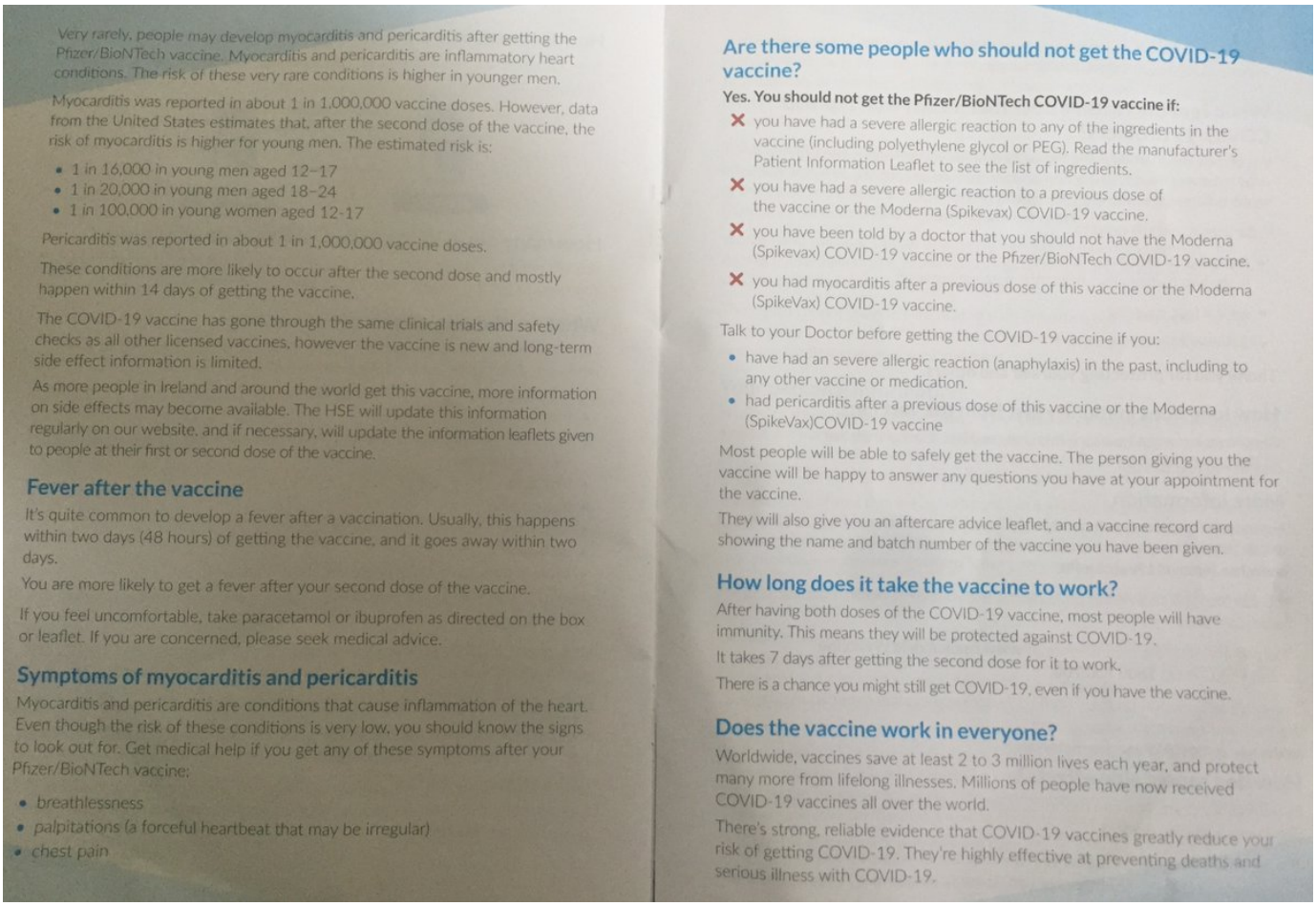
Bell's palsy is a rare side effect seen in more than 1 in 10,000 people.

Rarely, people who have had facial fillers may develop swelling of their face. This is seen in more than 1 in 10,000 people.

Serious side effects, like a severe allergic reaction, are extremely rare, seen in approximately 1 in 100,000 people. Your vaccinator is trained to treat very rare serious allergic reactions.

12. Symptoms of Myocarditis & Pericarditis

"There's strong, reliable evidence that COVID-19 vaccines greatly reduce your risk of getting COVID-19"



Very rarely, people may develop myocarditis and pericarditis after getting the Pfizer/BioNTech vaccine. Myocarditis and pericarditis are inflammatory heart conditions. The risk of these very rare conditions is higher in younger men.

Myocarditis was reported in about 1 in 1,000,000 vaccine doses. However, data from the United States estimates that, after the second dose of the vaccine, the risk of myocarditis is higher for young men. The estimated risk is:

- 1 in 16,000 in young men aged 12–17
- 1 in 20,000 in young men aged 18–24
- 1 in 100,000 in young women aged 12-17

Pericarditis was reported in about 1 in 1,000,000 vaccine doses.

These conditions are more likely to occur after the second dose and mostly happen within 14 days of getting the vaccine.

The COVID-19 vaccine has gone through the same clinical trials and safety checks as all other licensed vaccines, however the vaccine is new and long-term side effect information is limited.

As more people in Ireland and around the world get this vaccine, more information on side effects may become available. The HSE will update this information regularly on our website, and if necessary, will update the information leaflets given to people at their first or second dose of the vaccine.

Fever after the vaccine

It's quite common to develop a fever after a vaccination. Usually, this happens within two days (48 hours) of getting the vaccine, and it goes away within two days.

You are more likely to get a fever after your second dose of the vaccine.

If you feel uncomfortable, take paracetamol or ibuprofen as directed on the box or leaflet. If you are concerned, please seek medical advice.

Symptoms of myocarditis and pericarditis

Myocarditis and pericarditis are conditions that cause inflammation of the heart. Even though the risk of these conditions is very low, you should know the signs to look out for. Get medical help if you get any of these symptoms after your Pfizer/BioNTech vaccine:

- breathlessness
- palpitations (a forceful heartbeat that may be irregular)
- chest pain

Are there some people who should not get the COVID-19 vaccine?

Yes. You should not get the Pfizer/BioNTech COVID-19 vaccine if:

- ✕ you have had a severe allergic reaction to any of the ingredients in the vaccine (including polyethylene glycol or PEG). Read the manufacturer's Patient Information Leaflet to see the list of ingredients.
- ✕ you have had a severe allergic reaction to a previous dose of the vaccine or the Moderna (Spikevax) COVID-19 vaccine.
- ✕ you have been told by a doctor that you should not have the Moderna (Spikevax) COVID-19 vaccine or the Pfizer/BioNTech COVID-19 vaccine.
- ✕ you had myocarditis after a previous dose of this vaccine or the Moderna (SpikeVax) COVID-19 vaccine.

Talk to your Doctor before getting the COVID-19 vaccine if you:

- have had an severe allergic reaction (anaphylaxis) in the past, including to any other vaccine or medication.
- had pericarditis after a previous dose of this vaccine or the Moderna (SpikeVax)COVID-19 vaccine

Most people will be able to safely get the vaccine. The person giving you the vaccine will be happy to answer any questions you have at your appointment for the vaccine.

They will also give you an aftercare advice leaflet, and a vaccine record card showing the name and batch number of the vaccine you have been given.

How long does it take the vaccine to work?

After having both doses of the COVID-19 vaccine, most people will have immunity. This means they will be protected against COVID-19.

It takes 7 days after getting the second dose for it to work.

There is a chance you might still get COVID-19, even if you have the vaccine.

Does the vaccine work in everyone?

Worldwide, vaccines save at least 2 to 3 million lives each year, and protect many more from lifelong illnesses. Millions of people have now received COVID-19 vaccines all over the world.

There's strong, reliable evidence that COVID-19 vaccines greatly reduce your risk of getting COVID-19. They're highly effective at preventing deaths and serious illness with COVID-19.

13. "We do not know yet if having the vaccine stops you spreading the COVID-19 virus to others"

If you have a weakened immune system, there is no extra risk in taking the vaccine but it may not work as well for you.

When I get the vaccine, does that mean I won't spread COVID-19 to others?

We do not know yet if having the vaccine stops you spreading the COVID-19 virus to others. That is why it is important that we all continue to follow public health advice on how to stop the spread of the virus.

In particular, you still need to:

- follow social distancing guidelines (keep two metres apart from others where possible)
- wear a face covering
- wash your hands regularly

Thank you for protecting yourself and others.

How long does immunity last from the vaccine?

We do not know yet how long immunity will last. Clinical trials are ongoing to find this out.

More information

For more information, read the manufacturer's Patient Information Leaflet. This will be printed for you on the day you get your vaccine, or you can find it on **www.hse.ie/covid19vaccinePIL**

You can also talk to a health professional, like your GP (Doctor), Pharmacist or healthcare team.

You can also visit the HSE website at **www.hse.ie/covid19vaccine** or call HSELive on **1800 700 700**.

For more information on the COVID-19 vaccine, including materials in other formats and translation support, visit **www.hse.ie/covid19vaccinematerials**

How do I report side effects?

As with all vaccines, you can report suspected side effects to the Health Products Regulatory Authority (HPRA).

The HPRA is the regulatory authority in the Republic of Ireland for medicines, medical devices and other health products. As part of its role in the safety monitoring of medicines, the HPRA operates a system through which healthcare professionals or members of the public can report any suspected adverse reactions (side effects) associated with medicines and vaccines which have occurred in Ireland.

The HPRA strongly encourages reporting of suspected adverse reactions (side effects) associated with COVID-19 vaccines to support continuous monitoring of their safe and effective use. To report a suspected adverse reaction to the COVID-19 vaccine, please visit **www.hpra.ie/report**.

You can also ask your Doctor or a family member to report this for you. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

The HPRA cannot provide clinical advice on individual cases. Members of the public should contact their healthcare professional (their Doctor or Pharmacist) with any medical concerns they may have.

Your personal information

In order to administer the vaccine safely and to record all the necessary information to monitor and manage the vaccine, the HSE will be processing your personal information. All information processed by the HSE will be in accordance to the general laws and in particular the General Data Protection Regulation (GDPR) which came into force in 2018.

The processing of your data will be lawful and fair. It will only be processed for the specific purpose to manage the vaccinations. The principle of Data Minimisation has been applied. This means that only data that is necessary to identify you, book your appointment, record your vaccination and monitor its effects is being recorded.

You have the following rights as a data subject under the GDPR in respect of your personal data that are processed.

- Request information on and access to your personal data (commonly known as a 'data subject access request'). This enables you to receive a copy of the personal data we hold about you and to check that we are lawfully processing it.
- Request correction of the personal data that we hold about you. This enables you to have any incomplete or inaccurate information we hold about you corrected.
- Request erasure of your personal data. This enables you to ask us to delete or remove personal data where there is no good reason for us continuing to process it. You also have the right to ask us to delete or remove your personal information where you have exercised your right to object to processing.
- Object to processing of your personal data.

More information is available at **www.hse.ie/eng/gdpr**

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Published by HSE
on 9 August 2021

For the most up-to-date
information visit **www.hse.ie**

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Government of Ireland

15. Leaflet 3 29/7/2021

After your Comirnaty COVID-19 vaccine

COVID-19 VACCINE
Public Health Advice

After your Comirnaty (Pfizer/ BioNTech) COVID-19 vaccine

Thank you for protecting yourself and others by getting the vaccine. Now that you have had your vaccine, we ask you to read this document carefully, so you know how you can expect to feel in the next few days and where to get more information. Do read the COVID-19 vaccine information leaflet we gave you about the vaccine too.

We are also giving you a record of your vaccination today. **Please keep the record card safe.**

What might happen in the next few days?

Some people who got the vaccine that you got today will:

- have tenderness and swelling in the arm where they had the vaccine injection
- feel tired
- get a headache
- have muscle pain
- have joint pain
- have diarrhoea
- get a fever (temperature of 38 degrees Celsius or above).

A very small number of people who received the vaccine developed myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the heart lining).

The risk of these very rare conditions is higher in younger men. It is more likely to occur after the second dose and mostly happens within 14 days of getting the vaccine.

You should seek prompt medical assistance and mention your recent vaccination if you:

- are breathless
- have palpitations (a forceful heartbeat that may be irregular)
- have chest pain

As with all vaccines, you can report suspected side effects to the Health Products Regulatory Authority (HPRA). To report side effects to a COVID-19 vaccine, please visit **www.hpra.ie/report**

What if I have a fever or have aches and pains?
If you have a fever or you have aches and pains, you can take paracetamol or ibuprofen to help. However, if your fever lasts more than 48 hours or if you are still concerned, please seek medical advice. Do not take ibuprofen if you are pregnant.

Do I need to do anything before I get the second dose of the vaccine?
When you are having your next and final dose of the vaccine, please tell the vaccination team if there have been any changes in your medical history.

Bring your vaccination record card with you when going to get the second dose.
This will be in 21-28 days' time.

The good news
Getting a COVID-19 vaccine should protect you from the serious complications of COVID-19.

Vaccines teach your immune system to protect you from diseases. It is much safer for your immune system to learn this through vaccination than by getting COVID-19.

We are still learning
It takes 7 days after getting the second dose for it to work.

There is a small chance you might still get COVID-19 even if you have the vaccine.

We do not know yet if having the vaccine stops you spreading the virus to others, so you must continue to follow public health advice:

- follow social distancing guidelines
  (keep two metres apart from others where possible)
- wear a face covering
- wash your hands regularly.

Have a question?
If you are unsure about anything, or have any questions about the COVID-19 vaccine please ask your vaccinator today.

Visit **www.hse.ie/covid19vaccine** for more information on the COVID-19 vaccine.

Side effects
Please report any side effects to the HPRA at **www.hpra.ie/report**

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HSE

Rialtas na hÉireann
Government of Ireland

17. Another question I have frequently been asked is did I see the vials and box when I was in the walk in clinic

Unfortunately I did not

I hope everyone found this useful. As I said earlier I'm not up to speed on the approval process of Comirnaty but there many here that are.

18. You know the drill 😀 I write these 🧵 in my spare time and would really appreciate if you could retweet the very 1st tweet. Likes are great but retweets are required to reach as large an audience as possible to expose what is really going on behind the scenes. Many thanks.