

COVID-19: Vaccine side effects and reactions

Find out the side effects, the reported adverse events and allergic reactions to the Pfizer vaccine.

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Resources:

- Comirnaty (Pfizer) COVID-19 vaccine Consumer medicine information summary (PDF, 193 KB) (https://www.medsafe.govt.nz/Consumers/cmi/c/comirnaty.pdf)
- Comirnaty (Pfizer) COVID-19 vaccine New Zealand data sheet (PDF, 1.2 MB) (https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf)

How side effects are identified

In the COVID-19 vaccine clinical trials, people were followed very closely for side (adverse) effects for 2 months after the second dose of the vaccine. They compared the results between people who had and hadn't been vaccinated.

Ongoing monitoring of participants

To understand the long-term effectiveness, safety and side effects of the vaccine, participants in the clinical trials are then tracked for another two years. This is from their second dose of the Pfizer vaccine. Participants will:

- have their health monitored
- attend regular follow-up visits.

This clinical trial data is closely monitored by Pfizer/BioNTech and an independent group of experts called the Data Monitoring Committee.

Known side effects

Like all medicines, the vaccine may cause side effects in some people. Most side effects are mild and don't last long. They won't stop you from having the second dose or going about your daily life.

Some side effects may temporarily affect your ability to drive or use machinery.

Common side effects

In the clinical trials, common side effects were reported in every 1 in 10 to 1 in 100 people. These include:

- pain or swelling at the injection site
- feeling tired or fatigued
- headache
- · muscle aches
- chills
- · joint pain
- fever
- redness at the injection site
- nausea

Uncommon side effects

In the clinical trials, uncommon side effects were reported in every 1 in 100 to 1 in 1,000 people. These include:

enlarged lymph nodes

- feeling unwell
- · pain in limb
- insomnia
- · itching at injection site

Rare side effects

In the clinical trials, temporary one-sided facial drooping was reported in every 1 in 1,000 to 1 in 10,000 people.

Allergic reactions

Serious allergic reactions do happen but are extremely rare. They usually show soon after you've had your vaccine, which is why you need to wait at least 20 minutes. If you do have a serious allergic reaction, vaccinators are trained to manage these.

If you've had an allergic reaction to any vaccine or injection in the past, talk to your vaccinator.

When you're likely to experience a side effect

Most side effects show within a day or two after being vaccinated.

What you may feel	What can help	When this could start
Pain at the injection site, a headache and feeling tired and fatigued. These are the most commonly reported side effects.	Place a cold, wet cloth, or ice pack on the injection site for a short time.	Within 6 to 24 hours
	Do not rub or massage the injection site.	

What you may feel	What can help	When this could start
Muscle aches, feeling generally unwell, chills, fever, joint pain and nausea may also occur.	Rest and drink plenty of fluids	Within 6 to 48 hours
	Paracetamol or ibuprofen	
	can be taken, follow the manufacturer's instructions.	
	manufacturer 5 mstructions.	
	Seek advice from your	
	health professional if your	
	symptoms worsen.	

If you're concerned about how you're feeling

If you're unsure about your symptoms or if they get worse, call Healthline:

Phone 0800 358 5453 (tel:08003585453)

If you're concerned about your safety, call 111. Tell them you've had a COVID-19 vaccination so they can assess you properly.

Reported side effects in New Zealand

Adverse events following immunisation (AEFI) for the COVID-19 vaccine are reported to the Centre for Adverse Reactions Monitoring (CARM). We commonly know these as side effects.

Any side effects reported are suspected by the reporter to be caused by the vaccine. It doesn't always mean the vaccine did cause the side effect.

Centre for Adverse Reactions Monitoring (CARM) (https://nzphvc.otago.ac.nz/reporting/)

Medsafe closely monitors and releases a safety report showing this data each week. This shows the most common side effects that people in New Zealand experience after getting the COVID-19 vaccine.

Latest safety report from Medsafe

Timeframe: 20 February to 13 March 2021

COVID-19 vaccine administered: Pfizer/BioNTech (Comirnaty)

Total doses given: 22,588

Number of reports received on adverse events following immunisation (AEFI)

This shows the number of reports not the number of people who experienced an adverse event. One person may report on more than one symptom.

Total reports received: 215

Total reports that were serious: 6

• Total reports that were not serious: 209

Safety signals or potential safety issues identified: 0

The most reported adverse events

Of the 215 total reports, the top 10 reported adverse events were:

• Dizziness: 49 reports

· Headache: 37 reports

• Nausea: 36 reports

· Fainting: 22 reports

• Faintness: 9 reports

• Redness: 8 reports

• Fatigue: 8 reports • Fever: 8 reports

• Pain at the injection site: 8 reports

• Swelling: 8 reports

Serious adverse events reported

Of the 6 serious adverse events reported:

- 5 cases were allergic reactions and were managed appropriately.
- 1 was a reactogenicity reaction, where the patient experienced flu-like symptoms.

For the full reports, including definitions:

Safety report 2 - 13 March 2021 (https://www.medsafe.govt.nz/COVID-19/safety-report-1.asp) Safety report 1 - 6 March 2021 (https://www.medsafe.govt.nz/COVID-19/safety-report-1.asp)

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