

復星醫藥 / 德國藥廠BioNTech
Fosun Pharma/BioNTech

信使核糖核酸新冠疫苗
COVID-19 mRNA Vaccine

Comirnaty「復必泰」

(BNT 162b2)

接種須知
Vaccination Fact Sheet



1 What Comirnaty is and what it is used for¹

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.

The vaccine is authorized for use under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for the specific purpose of preventing COVID-19 infection. It has not been registered in Hong Kong under the Pharmacy and Poisons Ordinance (Cap. 138).

2 What you need to know before you receive Comirnaty¹

Comirnaty should not be given

- if you are allergic to previous dose of Comirnaty, or to the active substance or any of the other ingredients of this medicine including the following:

[(4-hydroxybutyl)azanediyl] bis(hexane-6,1-diy)l 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 injection



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. Vaccination should be delayed for individuals suffering from acute febrile diseases.
- 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.

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.

¹ Follow information provided by vaccine supplier

Children, adolescents and young adults

- Comirnaty is not recommended for children aged under 12 years.
- The Scientific Committee on Vaccine Preventable Diseases and the Scientific Committee on Emerging and Zoonotic Diseases under the Centre for Health Protection of the Department of Health joined by the Chief Executive's expert advisory panel (JSC-EAP) noted that there were overseas reports of mild myocarditis/pericarditis following vaccination with Comirnaty COVID-19 vaccine, and the probability on a possible link between the second dose and the onset of myocarditis among young adults. The Government will continue monitoring ongoing studies on this possible link.

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.

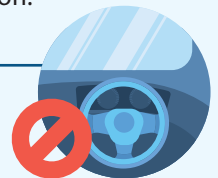


Pregnancy and breast-feeding

JSC-EAP acknowledged there is emerging data on the use of mRNA COVID-19 vaccines in pregnant and lactating women. Given there are no known risks associated with administering mRNA COVID-19 vaccines to lactating women, they are recommended to receive the BioNTech/Comirnaty vaccines (mRNA COVID-19 vaccines) as for the rest of the population. Pregnant women who consider BioNTech/Comirnaty vaccines (mRNA COVID-19 vaccines) should consult their obstetricians on the risks and benefits of vaccination.

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.



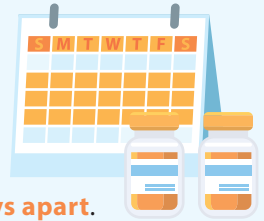
Wait until these effects have worn off before you drive or use machines.

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 given¹



- Comirnaty is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.
- You will receive **2 injections***, given **at least 21 days apart**.
- After the first dose of Comirnaty, you should receive a second dose of the same vaccine after 21 days to complete the vaccination course.

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

* JSC-EAP reviewed and updated the recommendation on COVID-19 vaccination for persons with previous COVID-19 infection. Previous COVID-19 infection usually confers immunity for at least 6 to 9 months for majority of patients. There is accumulating evidence showing that those previously infected with COVID-19 would be further protected by one dose of mRNA vaccine. After receiving one dose of mRNA vaccine, these persons may experience more systemic side effects (such as fatigue, headache, chills, muscle pain, fever and joint pain) when compared to those without prior infection. People who wish to receive mRNA vaccine should wait for at least 90 days after discharge from previous infection.

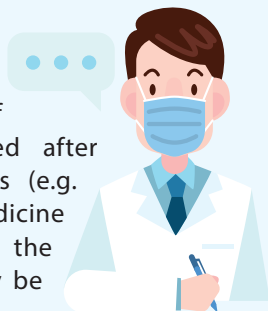
4 Possible side effects¹

Like all vaccines, Comirnaty can cause side effects, although not everybody gets them.

	Side effects	may affect
Very common	<ul style="list-style-type: none"> • injection site: pain, swelling • tiredness • headache • muscle pain Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.	more than 1 in 10 people
Common	<ul style="list-style-type: none"> • injection site redness • nausea • vomiting 	up to 1 in 10 people
Uncommon	<ul style="list-style-type: none"> • enlarged lymph nodes • feeling unwell • arm pain • insomnia • injection site itching • allergic reactions (e.g. rash, itching) 	up to 1 in 100 people
Rare	<ul style="list-style-type: none"> • temporary one sided facial drooping • allergic reactions (e.g. hives, swelling of the face) 	up to 1 in 1000 people
Not known	<ul style="list-style-type: none"> • severe allergic reaction 	cannot be estimated from the available data

5 Reporting of adverse events after immunization

The Department of Health (“DH”) has an adverse drug reaction (“ADR”) reporting system which receives adverse events following immunization (AEFIs) reports to monitor the safety of COVID-19 vaccines. If you have any suspected adverse event occurred after immunization, please alert healthcare professionals (e.g. doctors, dentists, pharmacists, nurses and Chinese Medicine Practitioners), when seeking their advice, to report the AEFIs to the DH if they consider that the AEFIs may be associated with the vaccination.



For continuously monitoring of the safety and clinical events associated with COVID-19 vaccination, your personal data collected for vaccination and your clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, may be accessed and used by DH and relevant organizations collaborated with the Government (including the University of Hong Kong) insofar as such information is necessary for the monitoring.



In situations when pain or redness at the injection site increases after 24 hours from injection; or your side effects are worrying you or do not seem to be going away in a few days, please contact your doctor.

If you do seek medical attention, make sure you tell the healthcare professionals about your vaccination details and show them your vaccination record card if available. Healthcare professionals will then make proper assessment and, if necessary, report any AEFI that is deemed medically significant to DH for further action and assessment.



Please allow the healthcare professional to report the AEFI, with your consent to passing the adverse event case information, personal and clinical data to DH for continuous monitoring the safety and clinical events associated with COVID-19 vaccination.

Message to the healthcare professionals:

Please conduct medical assessment and if you consider the AEFI associated with the vaccine is deemed medically significant, please report it to the Drug Office of the Department of Health via online reporting at the webpage

https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html

If the vaccine recipient experiences serious adverse event following immunization, please refer the recipient to hospital.

- I have read and understood all information as provided in the factsheet and the Statement of Purposes of Collection of Personal Data, and I consent to the administration of COVID-19 Vaccination to me / my child / my ward* under the COVID-19 Vaccination Programme; and the Department of Health and the relevant organizations (collaborated with the Government (including the University of Hong Kong))'s access to and use of (i) my / my child / my ward's* personal data contained herein and (ii) my / my child / my ward's* clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, for the purpose of continuously monitoring the safety and clinical events associated with COVID-19 Vaccination by the Department of Health insofar as such access and use are necessary for the purpose.

*Please delete as appropriate

For further information on vaccine information and side effects,
please visit the website at

www.covidvaccine.gov.hk



English



हिन्दी



नेपाली



اردو



ไทย



Bahasa Indonesia



Tagalog



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বাংলা ভাষা



Tiếng Việt