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Fosun Pharma / BioNTech

版本日期 Version date:

2022年3月4日  
4 March 2022

信使核糖核酸新冠疫苗  
COVID-19 mRNA Vaccine

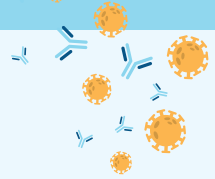
Comirnaty「復必泰」

(BNT 162b2)

接種須知  
Vaccination Fact Sheet



## 1 What Comirnaty is and what it is used for



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

Adult dose Comirnaty is given to adults and adolescents from 12 years of age and older<sup>@</sup>.

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).

@ For use of a fractional dose of the Comirnaty vaccine for adults in children aged 5 to 11 years, please refer to ["Supplementary notes on use of a fractional dose of Comirnaty vaccine for adults in children aged 5 to 11 years"](#).

## 2 What you need to know before you receive Comirnaty

### Comirnaty should not be given<sup>1</sup>

- 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-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 injection

### Warnings and precautions<sup>1</sup>

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 are feeling nervous about the vaccination process or 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.

<sup>1</sup> Follow information provided by vaccine supplier

- There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often occurred in younger males. 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

Adult dose Comirnaty is not recommended for children aged 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

Considering overseas recommendations and accumulating real world data on the safety of mRNA COVID-19 vaccines in pregnant and lactating women, the Scientific Committee on Vaccine Preventable Diseases and the Scientific Committee on Emerging and Zoonotic Diseases together with the Chief Executive's expert advisory panel (JSC-EAP) recommended them to receive the mRNA vaccines Comirnaty, including a third dose, as for the rest of the population.

## 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<sup>®</sup> into a muscle of your upper arm<sup>#</sup>.
  - # The JSC-EAP recommended intramuscular injection of the Comirnaty vaccine at mid-anterolateral thigh, especially for children and adolescents.
- You will receive **2 injections**, given **at least 21 days apart**<sup>\*</sup>.
- After the first dose of Comirnaty, you should receive a second dose of the same vaccine after 21 days to complete the vaccination course<sup>\*</sup>.

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

<sup>\*</sup> JSC-EAP recommended additional dose(s) (i.e. third/ and fourth dose) of COVID-19 vaccine for specific groups of persons. For details, please refer to the supplementary fact sheet "Recommendation for additional dose(s) of COVID-19 vaccination". Persons aged 5 to 17 years should receive the second dose of the Comirnaty vaccine at least 8 weeks (i.e. 56 days) after the first dose of Comirnaty vaccine. For persons recovered from COVID-19 infection, please refer to the ["Factsheet on COVID-19 Vaccination For Persons with Prior COVID-19 Infection"](#).

### 4 Possible side effects<sup>1</sup>

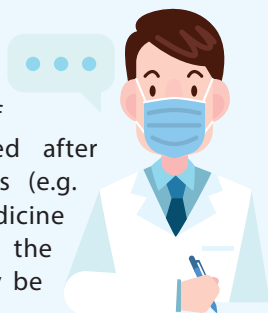
Like all vaccines, Comirnaty can cause side effects, although not everybody gets them.

	Side effects	may affect
<b>Very common</b>	<ul style="list-style-type: none"> <li>injection site: pain, swelling</li> <li>tiredness</li> <li>headache</li> <li>muscle pain</li> </ul> Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults. <ul style="list-style-type: none"> <li>chills</li> <li>joint pain</li> <li>diarrhoea</li> <li>fever</li> </ul>	<b>more than 1 in 10 people</b>
<b>Common</b>	<ul style="list-style-type: none"> <li>injection site redness</li> <li>nausea</li> <li>vomiting</li> </ul>	<b>up to 1 in 10 people</b>
<b>Uncommon</b>	<ul style="list-style-type: none"> <li>enlarged lymph nodes</li> <li>feeling unwell</li> <li>arm pain</li> <li>insomnia</li> <li>injection site itching</li> <li>allergic reactions (e.g. rash, itching)</li> <li>feeling weak or lack of energy/sleepy</li> <li>decreased appetite</li> <li>excessive sweating</li> <li>night sweats</li> </ul>	<b>up to 1 in 100 people</b>

	Side effects	may affect
<b>Rare</b>	<ul style="list-style-type: none"> <li>temporary one sided facial drooping</li> <li>allergic reactions (e.g. hives, swelling of the face)</li> </ul>	<b>up to 1 in 1,000 people</b>
<b>Very rare</b>	<ul style="list-style-type: none"> <li>myocarditis or pericarditis which can result in breathlessness, palpitations or chest pain</li> </ul>	<b>up to 1 in 10,000 people</b>
<b>Not known</b>	<ul style="list-style-type: none"> <li>severe allergic reaction</li> <li>extensive swelling of the vaccinated limb</li> <li>swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)</li> <li>a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)</li> <li>unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)</li> <li>decreased feeling or sensitivity, especially in the skin (hypoaesthesia)</li> </ul>	<b>cannot be estimated from the available data</b>

## 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](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 the vaccines and side effects,  
please visit the website at

**[www.covidvaccine.gov.hk](http://www.covidvaccine.gov.hk)**



English



हिन्दी



नेपाली



اردو



ไทย



Bahasa Indonesia



Tagalog



සිංහල භාෂාව



বাংলা ভাষা



Tiếng Việt

# Recommendation for additional dose(s) of COVID-19 vaccination:

Data from various overseas and local studies have shown that after a period of time from COVID-19 vaccination, the antibody level in human body would drop. As the protection conferred by vaccine may wane with time, the World Health Organization recommended specific groups of persons to receive the additional dose(s) of COVID-19 vaccines, in order to defend against the COVID-19 virus more effectively.

Local studies have shown that three doses of COVID-19 vaccines (i.e. Comirnaty (BioNTech) vaccine or CoronaVac (Sinovac) vaccine) are highly effective in reducing hospitalization and death across all age groups in the adult population.



**Taking reference from local experts' recommendations, eligible persons can receive the additional dose(s) of COVID-19 vaccine free of charge according to the recommendations below.**

## For CoronaVac (Sinovac) vaccine :

Age group	1 <sup>st</sup> dose	Interval	2 <sup>nd</sup> dose	Interval	3 <sup>rd</sup> dose	Interval	4 <sup>th</sup> dose
3 - 11 years old	●		●		●	N/A	✗
12 - 59 years old	★	28 days	★	● : 90 days ★ : 28 days	★	90 days (only for ★)	★
Aged 60 years or above						90 days	● ★

## For Comirnaty (BioNTech) vaccine :

Age group	1 <sup>st</sup> dose	Interval	2 <sup>nd</sup> dose	Interval	3 <sup>rd</sup> dose	Interval	4 <sup>th</sup> dose
5 - 11 years old	●	● : 56 days ★ : 21 days	● ★	28 days (only for ★)	★	N/A	✗
12 - 17 years old	★		● ★	● : 150 days ★ : 28 days	●	90 days (only for ★)	★
18 - 59 years old	●	21 days	●	● : 90 days ★ : 28 days	★		
Aged 60 years or above	★		★		● ★	90 days	● ★



**General public**  
(except COVID-19 recovered persons)



**Immunocompromised individuals\***  
(except COVID-19 recovered persons)



**Not yet recommended**

### Notes:

**After completion of the first two doses, those recommended to receive additional dose(s) may choose to receive the same brand or another brand of vaccine.**

If you have received covid-19 vaccine **outside Hong Kong, which was not CoronaVac or Comirnaty**, please consult the medical staff at the vaccination venue.

**Besides, please refer to the Government news announcement for the latest information on the vaccination venues which provide 3<sup>rd</sup> or 4<sup>th</sup> dose COVID-19 vaccines and the relevant arrangement.**

\* Immunocompromised persons include:

1. Cancer or hematological malignancy on active immunosuppressive treatment now or in the past 12 months
2. Recipients of solid organ transplant or stem cell transplant on immunosuppressive treatment
3. Severe primary immunodeficiency or on chronic dialysis
4. Advanced or untreated HIV disease
5. On active immunosuppressive drugs or immunosuppressive chemotherapy/radiotherapy in past 6 months



**If you are immunocompromised, please bring the relevant medical certificate to the designated vaccination venue on the day of your third or fourth dose vaccination in order to confirm that you are eligible for the vaccination**



Please refer to online version for most updated information. ▶