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.

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 Comirnaty

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:
  
  \[
  \begin{align*}
  &\text{(4-hydroxybutyl)azanediy|bis(hexane-6,1-diyl)}\|\text{bis} \\
  &\text{(2-hexyldecanoate)(ALC-0315)/2-[(polyethylene glycol)-2000]-}\text{N,} \\
  &\text{N-ditetradecylacetamide (ALC-0159)}/1,2-\text{Distearoyl-sn-glycero-3-phosphocholine (DSPC)}/\text{cholesterol} \\
  &\text{potassium chloride/potassium dihydrogen phosphate/sodium chloride/disodium phosphate dihydrate/sucrose/water for injection}
  \end{align*}
  \]

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 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.

1 Follow information provided by vaccine supplier
• 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 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 into a muscle of your upper arm.

  # The JSC-EAP recommended intramuscular injection of the Comirnaty vaccine at mid-anteerolateral thigh, especially for male children and male adolescents.

- 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 recommended an additional dose (i.e. third dose) of COVID-19 vaccine for persons aged 18 or above. For details, please refer to the supplementary fact sheet “Recommendation for 3rd dose COVID-19 vaccination”. Persons aged 12 to 17 years should receive the second dose of the Comirnaty vaccine at least 12 weeks (i.e. 84 days) after the first dose of Comirnaty vaccine. Persons recovered from COVID-19 infection are recommended to receive a second dose of Comirnaty vaccine (or CoronaVac) at least 180 days after the first dose; those with personal needs (e.g. travel to overseas countries) can receive the second dose at least 90 days after the first dose.

4 Possible side effects

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

<table>
<thead>
<tr>
<th>Side effects</th>
<th>may affect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very common</strong></td>
<td></td>
</tr>
<tr>
<td>injection site:</td>
<td>more than 1 in 10 people</td>
</tr>
<tr>
<td>pain, swelling</td>
<td></td>
</tr>
<tr>
<td>tiredness</td>
<td></td>
</tr>
<tr>
<td>headache</td>
<td></td>
</tr>
<tr>
<td>muscle pain</td>
<td></td>
</tr>
</tbody>
</table>

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

| **Common**                    | up to 1 in 10 people            |
| injection site redness        |                                 |
| nausea                        |                                 |
| vomiting                      |                                 |

| **Uncommon**                  | up to 1 in 100 people           |
| enlarged lymph nodes          |                                 |
| feeling unwell                |                                 |
| arm pain                      |                                 |
| insomnia                      |                                 |
| injection site itching        | allergic reactions (e.g. rash, itching)
| feeling weak or lack of energy/sleepy
| decreased appetite
| excessive sweating
<p>| night sweats                 |                                 |</p>
<table>
<thead>
<tr>
<th>Side effects</th>
<th>may affect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rare</strong></td>
<td></td>
</tr>
<tr>
<td>• temporary one sided facial drooping</td>
<td>up to 1 in 1000 people</td>
</tr>
<tr>
<td><strong>Not known</strong></td>
<td></td>
</tr>
<tr>
<td>• severe allergic reaction</td>
<td></td>
</tr>
<tr>
<td>• myocarditis or pericarditis which can result in breathlessness, palpitations or chest pain</td>
<td>cannot be estimated from the available data</td>
</tr>
<tr>
<td>• extensive swelling of the vaccinated limb</td>
<td></td>
</tr>
<tr>
<td>• swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)</td>
<td></td>
</tr>
</tbody>
</table>

## 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


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
COVID-19 vaccines protect individuals from severe illnesses and complications from COVID-19. In view of the latest Omicron situation and overseas experience, individuals who are not vaccinated should receive vaccination as soon as possible.

On 23 December 2021, the Joint Scientific Committees on Vaccine Preventable Diseases and Emerging and Zoonotic Diseases joined by the Chief Executive’s expert advisory panel (JSC-EAP) updated the recommendation for the vaccination arrangement for the third dose COVID-19 vaccines:

**Immunocompromised individuals:**
- A third dose of BioNTech(Comirnaty) vaccine is strongly recommended for certain groups of immunocompromised individuals* ≥12 years of age. Personal choice for the vaccines for the third dose is respected.
- The third dose should be administered at least 28 days from the second dose.

**Individuals aged 18 years and above who had received two doses of Comirnaty(BioNTech) or CoronaVac(Sinovac) vaccine:**
- A third dose of Comirnaty(BioNTech) vaccine is strongly recommended. Personal choice for the vaccines for the third dose is respected.
- The third dose is recommended to be administered as soon as possible 180 days after the second dose.
- Individuals with personal needs (e.g. travel to overseas countries, workers at increased risk for COVID-19 exposure and transmission because of occupational setting) can receive a third dose earlier with informed consent, but not less than 90 days after the second dose.

**Pregnant and lactating women:**
- Considering overseas recommendations and accumulating real world data on the safety of mRNA COVID-19 vaccines in pregnant and lactating women, they are recommended to receive the mRNA vaccines[Comirnaty(BioNTech)], including a third dose, as for the rest of the population.

**Notes:**
If you have received the 1st dose and/or 2nd dose vaccine outside Hong Kong, which was not CoronaVac(Sinovac) or Comirnaty(BioNTech), please consult the on-site doctor at the vaccination venue for suitability for a 3rd dose COVID-19 vaccine.

Besides, please refer to the Government news announcement for the latest information on the vaccination venues which provide 3rd dose COVID-19 vaccines and the relevant arrangement.

* Immunocompromised persons eligible for a third dose COVID-19 vaccine include the following groups:
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 dose vaccination in order to confirm that you are eligible for the vaccination.

Please refer to online version for most updated information.

Version date: 24 December 2021