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).

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:

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

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 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**

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) 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 Comirnaty vaccines (mRNA COVID-19 vaccines) as for the rest of the population. Pregnant women who consider 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 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*, 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 specific groups of people. For details, please refer to the supplementary fact sheet “Recommendation for 3rd dose COVID-19 vaccination”. Persons recovered from COVID-19 infection who wish to receive mRNA vaccine should wait for at least 90 days after discharge from the previous infection for the first dose. There is currently lack of data on the administration of additional dose(s) to them. They should discuss with their physicians and if given, an interval of at least 180 days between the two doses is recommended.

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 pain, swelling</td>
<td>chills, joint pain, diarrhoea,</td>
</tr>
<tr>
<td>tiredness</td>
<td>fever</td>
</tr>
<tr>
<td>headache</td>
<td>more than 1 in 10 people</td>
</tr>
<tr>
<td>muscle pain</td>
<td></td>
</tr>
<tr>
<td>Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.</td>
<td></td>
</tr>
<tr>
<td><strong>Common</strong></td>
<td></td>
</tr>
<tr>
<td>injection site redness</td>
<td>vomiting</td>
</tr>
<tr>
<td>nausea</td>
<td>up to 1 in 10 people</td>
</tr>
<tr>
<td><strong>Uncommon</strong></td>
<td></td>
</tr>
<tr>
<td>enlarged lymph nodes</td>
<td>allergic reactions (e.g. rash, itching)</td>
</tr>
<tr>
<td>feeling unwell</td>
<td>feeling weak or lack of energy/sleepy</td>
</tr>
<tr>
<td>arm pain</td>
<td>decreased appetite</td>
</tr>
<tr>
<td>insomnia</td>
<td>excessive sweating</td>
</tr>
<tr>
<td>injection site itching</td>
<td>night sweats</td>
</tr>
<tr>
<td></td>
<td>up to 1 in 100 people</td>
</tr>
</tbody>
</table>
### Side effects

<table>
<thead>
<tr>
<th>Rare</th>
<th>may affect</th>
</tr>
</thead>
<tbody>
<tr>
<td>temporary one sided facial drooping</td>
<td>up to 1 in 1000 people</td>
</tr>
<tr>
<td>allergic reactions (e.g. hives, swelling of the face)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>severe allergic reaction</td>
</tr>
<tr>
<td>myocarditis or pericarditis which can result in breathlessness, palpitations or chest pain</td>
</tr>
<tr>
<td>extensive swelling of the vaccinated limb</td>
</tr>
<tr>
<td>swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)</td>
</tr>
<tr>
<td>cannot be estimated from the available data</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
On 27th October 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) recommended the following vaccination arrangement for the third dose COVID-19 vaccines:

**Immunocompromised individuals:**
- An additional dose (i.e. 3rd dose) of COVID-19 vaccine (BioNTech(Comirnaty) vaccine for ≥12 years of age and Sinovac(CoronaVac) vaccine for ≥18 years of age) for certain groups of immunocompromised individuals*.
- The third dose should be administered at least 28 days from the second dose.
- It is noted that for those who had received two doses of Sinovac(CoronaVac) vaccine, a third dose of BioNTech(Comirnaty) vaccine may elicit a better immune response than Sinovac(CoronaVac) vaccine. BioNTech(Comirnaty) vaccine offers greater protection but personal preference is respected.

**Persons who have received two doses of Sinovac(CoronaVac) vaccines:**
- An additional dose (i.e. 3rd dose) of COVID-19 vaccine for those who had received two doses of Sinovac(CoronaVac) vaccine, in particular persons with a higher risk of infection including:
  - (i) elderly aged 60 or above;
  - (ii) healthcare workers;
  - (iii) workers at increased risk for COVID-19 exposure and transmission because of occupational setting (personnel participating in anti-epidemic related work; personnel providing cross-boundary transportation or working at control points and ports); and
  - (iv) persons with chronic illnesses.
- The third dose should be administered at least 180 days from the second dose.
- A third dose of BioNTech(Comirnaty) vaccine may elicit a better immune response than Sinovac(CoronaVac) vaccine. BioNTech(Comirnaty) vaccine offers greater protection but personal preference is respected.

**Persons who have received two doses of BioNTech(Comirnaty) vaccines:**
- An additional dose (i.e. 3rd dose) of COVID-19 vaccine for those aged 18 or above in the aforementioned higher risk populations who had received two doses of BioNTech(Comirnaty) vaccine.
- The third dose BioNTech(Comirnaty) vaccine should be administered at least 180 days from the second dose.
- A third dose of BioNTech(Comirnaty) is recommended but Sinovac(CoronaVac) vaccine can be given as third dose to respect personal preference or if indicated.

**Notes:**
- If you have received the 1st dose and/or 2nd dose vaccine outside Hong Kong, which was not CoronaVac or Comirnaty, 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.

Version date: 1 November 2021