

Comirnaty – COVID-19 mRNA Vaccine (Fosun Pharma/BioNTech)



Consent Form for the COVID-19 Vaccination Programme
– For children receiving fractional dose of Comirnaty, including children aged between 5 and 11 years old; and children who just turn 12 years with first dose given at 11 years

Before completing the consent form, please read the (1) Vaccination Fact Sheet and (2) FAQ on the following websites:

- (1) https://www.covidvaccine.gov.hk/pdf/COVID19VaccinationFactSheet_Comirnaty_ENG.pdf
 (2) https://www.covidvaccine.gov.hk/pdf/FAQ_children_adolescents_ENG.pdf

(1)

(2)



Please complete this form in BLOCK letters using black or blue pen and put a “√” in appropriate boxes and *delete as appropriate.

Part 1. Personal Details of Vaccine Recipient (as indicated on identity document)

Personal Information																																											
School Name: _____	Class: _____ Class No.: _____																																										
Name: _____ (English) (surname) (given name)																																											
_____	_____																																										
(Chinese) (surname) (given name)																																											
Date of Birth: ____/____/____ (DD/MM/YYYY)	Gender: _____																																										
Identity Document (Please put a “√” in the box and fill in the document number as appropriate)																																											
• If the vaccine recipient has Hong Kong Identity Card (HKIC), please fill in information of the HKIC • If the vaccine recipient does not have HK Identity card, please fill in the Hong Kong Birth Certificate Registration No.; but if the vaccine recipient was not born in Hong Kong, please fill in the relevant identity document number																																											
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<input type="checkbox"/> If the recipient is not the holder of the above documents, please enclose a <u>COPY</u> of other identity document.	Document number: _____																																										

Part 2: Consent to Administration of COVID-19 Vaccination

I consent to (a) the administration of COVID-19 Vaccination to **my child / my ward** * under the COVID-19 Vaccination Programme (see particulars in Part 3); and (b) the access and use by the Department of Health and the relevant organisations collaborated with the Government (including the University of Hong Kong) of **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 of 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.

Part 3: Particulars of COVID-19 Vaccination

Note: A consent form is required for each dose of vaccination

A. Type, Dose¹ and Dose Sequence of COVID-19 vaccination (Put a “✓” in the most appropriate box)

Comirnaty – COVID-19 mRNA Vaccine (Fosun Pharma/BioNTech) – Fractional dose¹		
<input type="checkbox"/> First dose	<input type="checkbox"/> Second dose	<input type="checkbox"/> Others, please specify: _____ dose

¹The dosage for children aged 5 to 11 years is one-third of a dose for adults, but the ingredient is the same as that for adults.

Children below 12 years of age who have received a one-third of an adult dose and will turn 12 years old by the time of their second dose, should continue to receive the same dosage for their second dose (i.e. one-third of the adult dose) in the Children Community Vaccination Centres. However, they can also choose to receive the full dose for their second dose, through on line booking (https://booking.covidvaccine.gov.hk/forms/index_tc.jsp), similar to other persons aged 12 years and above.

B. Comirnaty should not be given to persons with the following conditions

If the vaccine recipient has the following condition(s), please ✓ in the appropriate <input type="checkbox"/> below.	
● History of allergic reaction to previous dose of Comirnaty, or to the active substance or any of the other ingredients of this medicine ²	<input type="checkbox"/>

²Including [(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

Part 4: Declaration and Signature

To be completed by parent / guardian

I have read and I understood the information in the Vaccination Fact Sheet for the COVID-19 vaccine particularised in Part 3, including contraindications (and possible adverse events) of COVID-19 vaccination, the vaccine product is authorised under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for specified purpose for prevention of COVID-19 infection but has not been registered under the Pharmacy and Poisons Ordinance (Cap. 138), and agree on behalf of my child / ward* to receive the COVID-19 vaccine particularised in Part 3. I have had the opportunity to ask questions and all of my questions were answered to my satisfaction. I also fully understood my obligation and liability under this consent form and the Statement(s) of Purpose of Collection of Personal Data.

I understand that the use of fractional doses of Comirnaty – mRNA Vaccine on children aged five to 11 years old is not listed in the approved package insert of the Comirnaty authorized under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). This is an off-label use allowed in the Government programme under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap.599K) , having regard to the advice from panel(s) / committee(s) of experts appointed by the Government upon review of the current and anticipated epidemic situation, as well as the relevant efficacy and safety data published. The person who prescribes, dispenses or is responsible for the administering of the vaccine in fractional dose to my child / ward* acts in accordance with the Government’s direction in the Government programme.

I confirm that by signing underneath, I consent to (a) the administration of COVID-19 Vaccination to my child / my ward * under the COVID-19 Vaccination Programme (see particulars in Part 3); and (b) the access and use by the Department of Health and the relevant organisations collaborated with the Government (including the University of Hong Kong) of 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 of 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.

I declare the information provided in this form is correct.

I agree to provide my child / my ward’s* personal data in this form for the use by the Government for the purposes as set out in the “Statement of Purpose of Collection of Personal Data”. I understand that the Government may contact me to verify the information and the arrangement of the vaccination.

For Smart Identity Card holder: I agree to authorise the Healthcare Providers / public officers to read my child / my ward’s* personal data [limited to Hong Kong Identity Card No., Name (in English and Chinese), date of birth and date of issue of Hong Kong Identity Card] saved in the chip embodied in my/ my child / my ward’s* Smart Identity Card for the use by the Government for the purposes as set out in the “Statement of Purpose of Collection of Personal Data”.

This consent form shall be governed by and construed in accordance with the laws of Hong Kong Special Administrative Region and I shall irrevocably submit to the exclusive jurisdiction of the Courts of Hong Kong Special Administrative Region.

Signature of Parent / Guardian*: _____

Name of Parent / Guardian* (in English): _____

Relationship: _____

HKID/ Other Identity Document
- Document Type and Document No. of Parent/ Guardian*: _____

Contact Telephone No.: _____

Date: _____

Part 5: Reminder of the day of vaccination

- All vaccine recipients should bring (1) a completed consent form and (2) the ORIGINAL COPY of the relevant identity document on the day vaccination AND (3) Student handbook or student card with photo.
- An accompanying adult e.g. adult relative, domestic helper or school teacher is required to be present physically on the spot.
- Children and adolescents are recommended by experts to receive BioNTech vaccine intramuscularly at anterolateral aspect of mid-thigh, although their preference for an injection at upper arm would be respected. They can wear loose-fitting, easy to roll-up or other suitable clothing for ease of vaccination.

Statement of Purpose of Collection of Personal Data

The provision of personal data is voluntary. If you do not provide sufficient information, you may not be able to receive vaccination.

Purpose of Collection

1. The personal data provided will be used by the Government for one or more of the following purposes:
 - (a) checking with relevant government departments and organisations on the status of receiving COVID-19 vaccine;
 - (b) informing relevant government bureaux or departments and organisations for arranging vaccination and follow up after the vaccination;
 - (c) for creation, processing and maintenance of an eHealth (Subsidies) account, and the administration and monitoring of the COVID-19 vaccination programme, including but not limited to a verification procedure by electronic means with the data kept by the Immigration Department;
 - (d) transferring to the Department of Health and relevant organisations collaborated with the Government (including the University of Hong Kong) for continuous monitoring of the safety and clinical events associated with COVID-19 Vaccination under the COVID-19 Vaccination Programme;
 - (e) for statistical and research purposes;
 - (f) preventing, protecting against, delaying or otherwise controlling the incidence or transmission of the COVID-19 disease, including contact tracing; and
 - (g) any other legitimate purposes as may be required, authorised or permitted by law.

Classes of Transferees

2. The personal data you provided will be transferred to the Government and may also be disclosed by the Government to its agents, other organisations, and third parties for the purposes stated in paragraph 1 above, if required.

Access to Personal Data

3. You have the right to request access to and correction of your personal data under sections 18 and 22 and principle 6, schedule 1 of the Personal Data (Privacy) Ordinance (Cap. 486). The Department of Health may impose a fee for complying with a data access request.

Enquiries

4. Enquiries concerning the personal data provided, including the request for access and correction, should be addressed to:
Executive Officer (Programme Management and Vaccination Division)
Address: Centre for Health Protection, Block A, 2/F, 147C Argyle Street, Kowloon
Telephone No.: 2125 2045