

Communicable Diseases and Immunization Service 655 West 12th Avenue Vancouver, BC V5Z 4R4

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Date: February 11, 2021 Administrative Circular: 2021:06

ATTN: Medical Health Officers and Branch Offices

Public Health Nursing Administrators and Assistant Administrators

Holders of Communicable Disease Control Manuals

Re: Update to Communicable Disease Control Manual, Chapter 2: Immunization, Part 4 – Biological Products

Part 4 – Biological Products

COVID-19 Vaccines

COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech)

The product page has been revised as follows:

- Administration:
 - O Health Canada has issued an authorization to modify the Pfizer-BioNTech COVID-19 vaccine product labelling to indicate that after dilution, each vial contains six doses. This is a change from the initial authorization for five doses per vial. In the short term, vial labels and cartons may continue to state that a vial contains five doses. However, the information in the <u>Product</u> <u>Monograph</u> regarding the number of doses per vial after dilution supersedes the number of doses stated on the vial labels and cartons.
 - It is important to note, however, that withdrawal of a sixth dose is dependant, in part, on the type of syringes and needles used to withdraw doses from the vials. Low dead-volume syringes and/or needles should be used if available, as standard syringes and needles may not facilitate the extraction of a sixth dose from a single vial.
 - Content has been added regarding the pooling of residual vaccine volume from up to three vials to constitute a full dose provided the vials are from the same manufacturer and the same lot number. Further information on how to do this safely to minimize the risk of microbial contaminants and maintain product quality has been added as an addendum within the product page.
- Precautions:
 - Content added regarding individuals with suspected hypersensitivity or nonanaphylactic allergy to COVID-19 vaccine components.





Content added regarding the recommendation that tuberculin skin test (TST) and IGRA tests should be administered and read before COVID-19 immunization or delayed for at least 4 weeks after immunization. This is due to the theoretical risk that mRNA vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. COVID-19 immunization may take place at any time after all steps of the TST have been completed.

Please remove page numbers: 1-3 dated January 8, 2021 Please add new page numbers: 1-4 dated February 2021

COVID-19 mRNA Vaccine mRNA-1273 (Moderna)

The product page has been revised as follows:

- Administration:
 - Content added regarding the use of low dead-volume syringes/needles for obtaining an additional dose of vaccine (beyond 10 doses) from a single vial.
 - Content has been added regarding the pooling of residual vaccine volume from up to three vials to constitute a full dose provided the vials are from the same manufacturer and the same lot number. Further information on how to do this safely to minimize the risk of microbial contaminants and maintain product quality has been added as an addendum within the product page.
- Precautions:
 - Content added regarding individuals with suspected hypersensitivity or nonanaphylactic allergy to COVID-19 vaccine components.
 - Content added regarding the recommendation that tuberculin skin test (TST) and IGRA tests should be administered and read before COVID-19 immunization or delayed for at least 4 weeks after immunization. This is due to the theoretical risk that mRNA vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. COVID-19 immunization may take place at any time after all steps of the TST have been completed.
- Adverse Events:
 - Content added regarding the occurrence of delayed localized reactions with onset on or after day 8 following vaccination in a small percentage of vaccine recipients.

Please remove page numbers: 1-3 dated January 11, 2021 Please add new page numbers: 1-4 dated February 2021





COVID-19 After Care Sheet

- Additional content regarding local injection site reactions has been added, indicating
 that these are very common side effects following COVID-19 vaccination, and the
 possibility of a delayed local reaction starting on or after 8 days after receiving the
 vaccine can also occur.
 - Delayed reactions with pain, redness, swelling, and occasionally pruritus, at the injection site have been noted in BC. Such reactions were observed in the Moderna clinical trials in about 1% of vaccine recipients with onset on or after day 8 following vaccination, and were more likely to occur following the first dose than the second dose. These delayed reactions are thought to represent dermal hypersensitivity and resolve after 4-5 days. Vaccine recipients who have experienced these delayed local reactions have safely received the second dose. These delayed injection site reactions are not reportable events unless they meet the reporting criteria outlined in the BC Immunization Manual, Part 5: Adverse Events Following Immunization.

Please remove page numbers: 1-2 dated January 22, 2021 Please add new page numbers: 1-2 dated February 2021





BC Centre for Disease Control Provincial Health Services Authority

If you have any questions or concerns, please contact Stephanie Meier, Senior Practice Leader, BCCDC (telephone: 604-707-2577 / email: stephanie.meier@bccdc.ca).

Sincerely.

Monika Naus MD MHSc FRCPC FACPM

Medical Director

Communicable Diseases & Immunization Service

BC Centre for Disease Control

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