First Nations and Inuit Health Branch

Internal Use: FNIHB Nursing Stations Only
December 15, 2022

Interim Stocking of Evusheld (tixagevimab and cilgavimab) Information Sheet

Indication:

Evusheld is indicated for the treatment of mild to moderate coronavirus disease 2019 (COVID-19), in adults and adolescents (12 years of age and older weighing at least 40 kg) who are at high risk for progressing to hospitalization and/or death. (Evusheld is also approved for pre-exposure prophylaxis of COVID-19 for select populations.)

Nurses are to refer to ISC LRRCN Eligibility Interim COVID Therapeutic Mgmt document for assessment and management of COVID-19

Warnings and Considerations:

- Reduced Efficacy:
  - Evusheld may have reduced efficacy against some variants of SARS-CoV -2. Evusheld will be prescribed in consultation with RAAPID for local epidemiology and individual exposure to circulating variants.
    - Inform patients who receive Evusheld about the potential for a lack of effectiveness against certain variants.
    - Instruct patients to seek medical advice if signs or symptoms of COVID-19 occur, persist or worsen.
- Cardiac Adverse Events:
  - There is a small increased risk of cardiovascular events in those who have are at high risk for cardiovascular or thromboembolic event.
    - Assess patients for history of cardiovascular events, including MI, heart failure, thromboembolic events.
    - Inform the prescriber about patient history of CV events
    - Instruct the patient to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular or thromboembolic event.
- Bleeding Disorders:
  - Evusheld should be given with caution to clients with thrombocytopenia or any coagulation disorder.

Special Populations:

- Pregnancy and Lactation:
  - Lack of studies in this population. Prescribing will be done in consultation with obstretics.
- Pediatrics:
  - Evusheld may be given in pediatrics age 12 years and older with a consult by NP from the FNIHB MOH and Pediatric Infectious Disease.

Storage:

Storage Prior to Injection
- Store unopened vials refrigerated at 2°C to 8°C in original carton.
- Do not freeze.
- Do not shake.

The prepared syringes should be administered immediately. If immediate administration is not possible, the total time from vial puncture to administration should not exceed 4 hours, either:
- in a refrigerator at 2ºC to 8ºC or at room temperature up to 25ºC.

Contraindications:
Evusheld is contraindicated in individuals who have a history of severe hypersensitivity reactions, including anaphylaxis, to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a list of ingredients, refer to the Health Canada Product Monograph for Evusheld.

Dosage:

The recommended dose for treatment is 600 mg of EVUSHELD, administered as two separate 3.0 mL, sequential, injections of:

300 mg of tixagevimab and 300 mg of cilgavimab

Evusheld should be given as soon as possible after a positive viral test for SARS-CoV-2 and **within 7 days** after the onset of symptoms .

Administration:

For intramuscular injection.

Visually inspect the vials for particulate matter and discolouration. Both tixagevimab and cilgavimab are clear to opalescent, colourless to slightly yellow solutions. Discard the vials if the solution is cloudy, discoloured or visible particles are observed. Do not shake the vials.

Preparation and Administration of tixagevimab/cilgavimab **600 mg total dose:**

Two cartons	**tixagevimab 300mg**	tixagevimab 150 mg/1.5 mL vial (dark grey cap) **x 2**	Withdraw 1.5 mL from each vial into a syringe for total volume 3 mL#	Inject tixagevimab intramuscularly (**preferably gluteal muscle**)**
	cilgavimab 300 mg	cilgavimab 150 mg/1.5 mL vial (white cap) **x 2**	Withdraw 1.5 mL from each vial into a syringe for total volume 3 mL#	Inject cilgavimab intramuscularly (**preferably gluteal muscle**)**

#Discard remainder of vial.
**Administer tixagevimab and cilgavimab as separate injections.

Monitoring Requirements:

Observe the client receiving the IM injections and monitor the client 60 minutes following the injections for adverse effects.

Adverse Effects:
It may be difficult to distinguish between adverse effects of Evusheld and signs and symptoms of COVID-19. Clients should be monitored for adverse events during and post IM injections. Following the observation period, clients should be provided with advice post injection requirements, including adverse effects and who to contact for more information.

The most frequently reported adverse reactions:

- injection site reaction (1.3%).
  - Pain from inserting the needle, pruritus, bruising of the skin, soreness, or swelling at the injection site.
- Hypersensitivity and Anaphylaxis (1%)
  - Includes rash and urticaria, anaphylaxis is rare
  - If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medicinal products and/or supportive therapy.

REFERENCES:

1. AstraZeneca Canada. EVUSHELD™ (tixagevimab and cilgavimab injection) Canadian product monograph. April 14, 2022. https://covid-vaccine.canada.ca/info/pdf/EVUSHELD™-pm-en.pdf
2. CADTH Drug Implementation Advice Tixagevimab and Cilgavimab (Evusheld); 2022
3. Manitoba Shared Health, Evusheld: Information for Health-care Providers (for prophylaxis); July 29, 2022.