Ebola Vaccine

Ebola Zaire vaccine

Date: December 4, 2023

This policy is evergreen and will be updated as new information becomes available.

Please consult the Product Monograph¹ for further information about the vaccine.

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<th>ERVEBO®</th>
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<tr>
<th>Manufacturer</th>
<th>Merck</th>
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**Authorization and access**

Special authorization and access procedures must be followed:

- There is a limited supply of vaccine available as post-exposure prophylaxis to persons in Canada who have been exposed to Ebola virus in Canada.
- The Ebola vaccine is stockpiled in Canada’s National Emergency Strategic Stockpile (NESS) and is only available through the Special Access Program (SAP).
- In consultation with the CMOH, an MOH can seek authorization from Health Canada’s SAP Program to access vaccine.
- The Office of the Chief Medical Officer of Health (OCMOH) must be notified by the fastest means possible of all cases for which Ebola vaccine is required.

Available on a 24-hour basis from Alberta Health by calling OCMOH pager: 780-638-3630.

**Licensed use**

Individuals 18 years of age and older.

**Off-license use**

A single dose of ERVEBO® may be considered for use in infants, children and adolescents who have been exposed to Ebola virus (EBOV) (Orthoebolavirus zairense formerly Zaire ebolavirus) in Canada.²

**Indications for use of vaccine**

- Post-exposure prophylaxis to persons who have been exposed to EBOV in Canada.
- ERVEBO® should be given within 72 hours of exposure but may be given up to 10 days post-exposure.

For information about the disease refer to Public Health Notifiable Disease Management Guidelines – Ebola.³

**Dose**

- 1mL¹

**Route**

Intramuscular injection¹

**Schedule**

- ERVEBO® should be given within 72 hours of exposure but may be given up to 10 days post-exposure.
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<th>Contraindications</th>
<th>• Known severe hypersensitivity to any component of the vaccine, including any non-medicinal ingredient, rice protein, or component of the container.</th>
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| Precautions      | • Immunization should be postponed in subjects experiencing moderate or severe febrile illness. The presence of a minor infection should not result in deferral of vaccination.  
• Vaccine recipients should avoid donating blood for 6 weeks post-immunization.  
• This vaccine is not indicated for use against the other Ebola viruses, such as Sudan virus or Bundibugyo virus, or related filoviruses, such as Marburg virus.  
• There are limited data on safety and efficacy of ERVEBO® in immunocompromised individuals. However, ERVEBO® may be considered as postexposure prophylaxis following exposure, occupational or otherwise, to EBOV in Canada.  |
| Pregnancy        | • There are limited safety data from the use of ERVEBO® in pregnant individuals, or in individuals who became pregnant after receiving the vaccine. The safety of ERVEBO® has not been established in pregnant people. Nevertheless, given the seriousness of Ebola virus disease (EVD), the vaccine may be considered for pregnant individuals who have had an exposure to EBOV, occupational or otherwise, in Canada.  
• Pregnancy should be avoided for 2 months following immunization. Women of child-bearing potential should use an effective contraceptive method.  |
| Lactation        | • It is unknown whether the vaccine virus is secreted in human milk.  
• There are limited safety data from the use of ERVEBO® in breastfeeding individuals. The safety of ERVEBO® has not been established in breastfeeding individuals. Nevertheless, given the seriousness of EVD, the vaccine may be considered for breastfeeding individuals who have had an exposure to EBOV, occupational or otherwise, in Canada.  
• A risk to the newborns/infants from breast-feeding by vaccinated mothers cannot be excluded.  |
| Possible reactions| See Product Monograph  |
| Administration with Other Products | • The administration of ERVEBO® with other vaccines is not recommended for the following reasons:  
  o there are no data on co-administration of ERVEBO® with other vaccines,  
  o the potential for immune interference, and  
  o the need to monitor for potential symptoms of EVD and ERVEBO® adverse events.  
• Immune globulin (IG), blood or plasma transfusions should not be given concomitantly with ERVEBO®. Administration of immune globulins, blood or plasma transfusions administered 3 months before or up to 1 month after ERVEBO® administration may interfere with the expected immune response.  |
| Storage and Handling | • Store and transport frozen at -80°C to -60°C. Do not store or transport outside the recommended temperature range.  |
- After thawing, the vaccine should be used immediately; however, in-use
  stability data have demonstrated that once thawed, the vaccine can be stored
  for up to 14 days at 2°C to 8°C prior to use.¹

- At the end of 14 days, the vaccine should be used or discarded. Upon removal
  from the freezer, the product should be marked with both the date that it was
  taken out of the freezer and also a new discard date (in place of the labelled
  expiry date).¹

- Once thawed, the vaccine cannot be re-frozen.¹

- Keep the vial in the outer carton to protect from light.¹

- The thawed vial should then be gently inverted several times prior to
  withdrawal with the syringe.¹

- The vaccine should appear as a colorless to slightly brownish-yellow liquid
  with no particulates visible. Discard the vaccine if particulates are present.¹

**Program notes**

- November 9, 2022 – Licensed for use in Canada.

**References**

