Ebola Zaire Vaccine Live

AHFS Class: 80:12 — Vaccines (tofc-80)

Ebola Zaire Vaccine Live *(AHFS DI)*

Ebola Zaire Vaccine, Live

Brands: Ervebo®

Introduction

Ebola Zaire vaccine live is a live, attenuated virus vaccine that contains replication-competent, recombinant vesicular stomatitis virus (VSV).[1,3,4,]

Uses

▪ Ebola Zaire vaccine live has the following uses:

Ebola Zaire vaccine live is indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 12 months of age and older.[1,]

▪ Ebola Zaire vaccine live has the following limitations of use:

The duration of protection conferred by Ebola Zaire vaccine live is unknown.[1,]

Ebola Zaire vaccine live does not protect against other species of *Ebolavirus* or against *Marburgvirus*.[1,]

Effectiveness of the vaccine when administered concurrently with antiviral medication, immune globulin, and/or blood or plasma transfusions is unknown.[1,]

Dosage and Administration

▪ General

Ebola Zaire vaccine live is available in the following dosage form(s) and strength(s):

Suspension, for IM use: Single-dose vial containing one 1-mL dose.[1,]

▪ Dosage

It is essential that the manufacturer's labeling be consulted for more detailed information on dosage and administration of this drug. Dosage summary:

Adults

Dosage and Administration.

For IM administration only, preferably into the deltoid area of the non-dominant arm.[1,]

Administer a single 1-mL dose.[1,]

Cautions

▪ Contraindications

Do not administer to individuals with a history of severe allergic reaction (e.g., anaphylaxis) to any component of Ebola Zaire vaccine live, including rice protein.[1,]

▪ Warnings/Precautions

Management of Acute Allergic Reactions

Among 18,616 individuals vaccinated with at least one dose of Ebola Zaire vaccine live in clinical trials, there were two reports of anaphylaxis.[1,]

Monitor individuals for signs and symptoms of hypersensitivity reactions following vaccination with Ebola Zaire vaccine live.[1,]

Appropriate medical treatment and supervision must be available in case an anaphylactic reaction occurs following administration of the vaccine.[1,]

Immunocompromised Individuals

The safety and effectiveness of Ebola Zaire vaccine live have not been assessed in immunocompromised individuals.[1,]

The effectiveness of Ebola Zaire vaccine live in immunocompromised individuals may be diminished.[1,]

The risk of vaccination with Ebola Zaire vaccine live, a live virus vaccine, in immunocompromised individuals should be weighed against the risk of disease due to *Zaire ebolavirus*.[1,]

Transmission of Vaccine Virus

Because Ebola Zaire vaccine live contains replication-competent, recombinant VSV, transmission of the vaccine virus to close contacts is theoretically possible.[1,3,] Data on the transmissibility of the vaccine virus from the vaccinee to susceptible contacts (humans and animals) are not available to date,[3,]

Detection of vaccine virus RNA in vaccinees using reverse transcription polymerase-chain reaction (RT-PCR) was used as a surrogate for potential vaccine virus transmissibility.[3,] Following administration of Ebola Zaire vaccine live, the vaccine virus RNA has been detected by RT-PCR in blood, saliva, urine, synovial fluid, and fluid from skin vesicles of some vaccinees.[1,3,]

Vaccine virus viremia was evaluated in 186 individuals enrolled in 7 clinical studies who were vaccinated with Ebola Zaire vaccine live. Vaccine virus RNA was detected by RT-PCR in the plasma of most vaccinees from days 1 to 7 after vaccination; one individual had a positive plasma RT-PCR result 14 days after vaccination.[1,]

Shedding of vaccine virus into the urine or saliva was evaluated in 359 individuals enrolled in 8 clinical studies who were vaccinated with Ebola Zaire vaccine live or lower-dose formulations. Vaccine virus RNA was detected by RT-PCR in the urine or saliva of some individuals at time points ranging from day 1 through day 14 postvaccination.[1,] In the 3 studies that assessed shedding at Day 28, no samples tested positive.[1,] In Study 6, 31.7% (19/60) of participants 12 months through 17 years of age enrolled in a substudy shed vaccine virus in saliva following vaccination.[1,] Viral shedding was greatest on Day 7 and declined thereafter, with no shedding detected after Day 28.[1,]

Laboratory Test Interference

Following vaccination with Ebola Zaire vaccine live, individuals may test positive for anti-Ebola glycoprotein (GP) antibody and/or Ebola GP nucleic acid or antigens. GP-based testing may have limited diagnostic value during the period of vaccine virus viremia, in the presence of vaccine-derived Ebola GP, and following antibody response to the vaccine.[1,] Therefore, diagnostic testing for EVD in vaccinated individuals should include nonglycoprotein targets.[3,]

Limitations of Vaccine Effectiveness

Vaccination with Ebola Zaire vaccine live may not protect all individuals. Vaccinated individuals should continue to adhere to infection control practices to prevent *Zaire ebolavirus* infection and transmission.[1,3,]

Ebola Zaire vaccine live does not provide protection against other species of *Ebolavirus* or against *Marburgvirus*.[1,]

Duration of Immunity

The duration of protection against *Zaire ebolavirus* infection after vaccination with Ebola Zaire vaccine live is not known.[3,4,]

Specific Populations

Pregnancy.

Risk Summary: There are no adequate and well-controlled studies of Ebola Zaire vaccine live in pregnant women, and human data available from clinical trials with Ebola Zaire vaccine live are insufficient to establish the presence or absence of vaccine-associated risk during pregnancy. The decision to vaccinate a woman who is pregnant should consider the woman's risk of exposure to *Zaire ebolavirus*.[1,]

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.[1,]

Clinical Considerations: Fetal and neonatal outcomes are universally poor among pregnant women infected with *Zaire ebolavirus*. The majority of such pregnancies end in miscarriage or stillbirth. In pregnancies where live birth does occur, neonates generally do not survive.[1,]

The potential for transmission of the vaccine virus from a vaccinated mother to the fetus/neonate is unknown.[1,]

Lactation.

Risk Summary: Human data are not available to assess the impact of Ebola Zaire vaccine live on milk production, its presence in breast milk, or its effects on the breast-fed child.[1,]

The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for Ebola Zaire vaccine live and any potential adverse effects on the breast-fed child from Ebola Zaire vaccine live or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.[1,]

Pediatric Use.

The safety and effectiveness of Ebola Zaire vaccine live in individuals younger than 12 months of age have not been established.[1,]

Geriatric Use.

Clinical studies of Ebola Zaire vaccine live did not include sufficient numbers of adults 65 years of age and older to determine whether they respond differently from younger individuals.[1,]

Across the clinical development program, a total of 554 individuals 65 years of age and older received at least one dose of Ebola Zaire vaccine live.[1,]

▪ Common Adverse Effects

The most commonly reported local and systemic adverse events in clinical trials of individuals 18 years of age and older: injection-site pain (70%); headache (55%); feverishness (39%); muscle pain (33%); somnolence, reduced activity, fatigue (26%); joint pain, arthralgia (19%); chills (17%); injection-site swelling (17%); decreased appetite (15%); abdominal pain (13%); injection-site redness (12%); nausea (10%); arthritis (5%); vomiting (4%), rash (4%); abnormal sweating (3%) and mouth ulceration (2%).[1,]

The most commonly reported local and systemic adverse events in clinical trials of individuals 12 months through 2 years of age: feverishness (83%); crying (31%); decreased appetite (27%); injection-site pain (26%); somnolence, reduced activity, fatigue (20%); diarrhea (19%); vomiting (17%); irritability (11%); screaming (10%); mouth ulceration (6%); chills (5%); injection-site swelling (5%); headache (4%); abdominal pain (2%); abnormal sweating (2%) and injectionsite erythema (1%).[1,]

The most commonly reported local and systemic adverse events in clinical trials of individuals 3 years through 11 years of age: feverishness (65%); headache (50%); injection-site pain (40%); decreased appetite (24%); somnolence, reduced activity, fatigue (22%); abdominal pain (21%); chills (14%); myalgia (12%); vomiting (11%);dizziness (8%); nausea (8%); injection-site pruritus (7%); crying (3%); arthralgia (3%); diarrhea (3%); injection-site swelling (3%); abnormal sweating (1%); mouth ulceration (2%) and irritability (1%).[1,]

The most commonly reported local and systemic adverse events in clinical trials of individuals 12 years through 17 years of age: headache (59%); injection-site pain (52%); feverishness (48%); myalgia (30%); somnolence, reduced activity, fatigue (28%); decreased appetite (21%); chills (19%); dizziness (17%); abdominal pain (16%); arthralgia (16%); nausea (8%); abnormal sweating (5%); diarrhea (4%); vomiting (4%); injection-site pruritus (3%); injection-site swelling (3%) and mouth ulceration (2%).[1,]

Drug Interactions

▪ Specific Drugs

It is essential that the manufacturer's labeling be consulted for more detailed information on interactions with this drug, including possible dosage adjustments. Interaction highlights:

Please see product labeling for drug interaction information.

Actions

▪ Mechanism of Action

Ebola Zaire vaccine live is a live, attenuated virus vaccine that contains replication-competent, recombinant VSV created by replacing the gene encoding the VSV envelope glycoprotein with the gene encoding the envelope glycoprotein of *Ebolavirus* species *Zaire ebolavirus* (Kikwit 1995 strain). The vaccine also contains rice-derived recombinant serum albumin.[1,3,]

Ebola Zaire vaccine live does not contain whole *Ebolavirus* and cannot cause EVD.[4,]

Administration of Ebola Zaire vaccine live results in an immune response and protection from disease caused by *Zaire ebolavirus*. The relative contributions of innate humoral and cell-mediated immunity to protection from *Zaire ebolavirus* are unknown.[1,]

A measure of the immune response to Ebola Zaire vaccine live that confers protection against EVD is unknown.[1,] Three studies assessed antibody responses to the vaccine and included 477 participants in Liberia, 506 participants in Sierra Leone, and 915 participants in the US, Canada, and Spain (865 were in the US). *Zaire ebolavirus* (Kikwit) GP-specific IgG was detected by enzyme linked immunosorbent assay (GP-ELISA).[1,] Vaccine virus neutralizing antibody was detected by a plaque reduction neutralization test (PRNT).[1,] Antibody responses among vaccine recipients in the US, Canada, and Spain were similar to those reported in vaccine recipients in Liberia and Sierra Leone.[1,]

Clinical efficacy of Ebola Zaire vaccine live was assessed in an open-label, randomized cluster (ring) vaccination study conducted in the Republic of Guinea during the 2014 outbreak.[1,] Each cluster was composed of contacts of individuals with laboratory-confirmed EVD and contacts of these contacts. Clusters were randomized to receive either an "immediate" vaccination or a 21-day "delayed" vaccination.[1,] In the primary efficacy analysis, 3537 participants 18 years of age and older were considered contacts and contacts of contacts of an index case with laboratory-confirmed EVD; of these, 2108 were included in 51 immediate-vaccination clusters and 1429 were included in 46 delayed-vaccination clusters.[1,] The number of cases of laboratory-confirmed EVD that occurred between days 10 and 31 post-randomization ir those in the immediate-vaccination clusters was compared to the number in delayed-vaccination clusters.[1,] There were no cases of confirmed EVD in the immediate-vaccination clusters, and 10 cases of confirmed EVD in a total of 4 delayed-vaccination clusters.[1,]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus) (in English and Spanish; written at a 6th- to 8th-grade reading level).

Advise vaccine recipient to read the FDA-approved patient labeling (Patient Information).[1,]

Ebola Zaire vaccine live has not been demonstrated to provide protection against disease caused by viruses other than *Zaire ebolavirus*. After vaccination with Ebola Zaire vaccine live, individuals at risk should continue to protect themselves from exposure to *Zaire ebolavirus*.[1,]

Ebola Zaire vaccine live may not protect all vaccinated individuals.[1,]

Transmission of vaccine virus is a theoretical possibility. Vaccine virus RNA has been detected in blood, saliva, or urine for up to 14 days after vaccination. The duration of shedding is not known; however, samples taken 28 days after vaccination tested negative. Vaccine virus RNA has been detected in fluid from skin vesicles that appeared after vaccination.[1,]

Importance of informing healthcare provider of any history of allergic reaction to Ebola Zaire vaccine live, rice protein, or any ingredients in the vaccine.[2,]

Importance of informing healthcare provider if potential vaccinee has a weakened immune system, is taking any medications or treatments that might weaken the immune system, or has close contact with anyone who has a weakened immune system.[2,]

Advise vaccine recipient to immediately seek medical attention if any signs or symptoms of a hypersensitivity reaction occur after vaccination.[1,]

Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or http://www.vaers.hhs.gov (http://www.vaers.hhs.gov) .[1,]

Importance of women informing clinicians if they are or plan to become pregnant or plan to breast-feed.[2,]

Additional Information

AHFS *First Release*®. For additional information until a more detailed monograph is developed and published, the manufacturer's labeling should be consulted. It is *essential* that the manufacturer's labeling be consulted for more detailed information on usual uses, dosage and administration, cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and acute toxicity.

Preparations

Ebola Zaire vaccine live is not commercially available in the US, but is stored and made available for US civilians.[3,] For information on how to request the vaccine, consult the CDC drug service at https://www.cdc.gov/laboratory/drugservice/formulary.html (https://www.cdc.gov/laboratory/drugservice/formulary.html) or CDC's Viral Special Pathogens Branch (VSPB) at spathvax@cdc.gov.[3,]

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Ebola Zaire Vaccine, Live (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Ebola+Zaire+Vaccine%2C+Live&collapse=1)

Parenteral

Suspension, for IM use

≥72 million PFU of vaccine virus (recombinant modified vesicular stomatitis virus) per mL

Ervebo®, Merck (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=Merck&collapse=1)

Related Resources

AHFS Patient Medication Information (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Ebola%20Zaire%20Vaccine%20Live) and other related patient health topics (MedlinePlus)
ASHP Drug Shortages Resource Center (https://www.ashp.org/Drug-Shortages)
CCRIS (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+ccris:%%22Ebola%20Zaire%20Vaccine%20Live%%22) (Chemical Carcinogenesis Research Information System)
ChemID*plus* (https://chem.nlm.nih.gov/chemidplus/name/Ebola%20Zaire%20Vaccine%20Live)
Biochemical Data Summary (http://www.drugbank.ca/unearth/q?utf8=%%E2%%9C%%93&query=Ebola%20Zaire%20Vaccine%20Live&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withdrawn=1&
(US and Canada)
Clinical Trials (https://www.clinicaltrials.gov/ct/search?submit=Search&term=Ebola%20Zaire%20Vaccine%20Live)
DailyMed (https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=Ebola%20Zaire%20Vaccine%20Live) (drug labels)
DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%%22Ebola%20Zaire%20Vaccine%20Live%%22) (Developmental and Reproductive Toxicology Database)
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=Ebola%20Zaire%20Vaccine%20Live) (approval information)
European Medicines Agency (https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=Ebola%20Zaire%20Vaccine%20Live)
FDA National Drug Code Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Ebola%20Zaire%20Vaccine%20Live&collapse=1)
FDA Recalls, Market Withdrawals, and Safety Alerts (https://www.fda.gov/Safety/Recalls/default.htm)
HSDB (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:%%22Ebola%20Zaire%20Vaccine%20Live%%22) (Hazardous Substances Data Bank)
Inxight Drugs (https://drugs.ncats.io/substances?q=%%22Ebola%20Zaire%20Vaccine%20Live%%22) (National Center for Advancing Translational Sciences)
LactMed (drug effects on breastfeeding) (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%%28@na+%%22Ebola%20Zaire%20Vaccine%20Live%%22+%%29)

New Drug Approvals (https://ahfs.ashp.org/drug-assignments.aspx)
Orange Book (https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?panel=0&drugname=Ebola%20Zaire%20Vaccine%20Live) (therapeutic equivalence)
PharmGKB (https://www.pharmgkb.org/search?connections&gaSearch=Ebola%20Zaire%20Vaccine%20Live&query=Ebola%20Zaire%20Vaccine%20Live&type=chemical) (Pharmacogenomic data from PharmGKB)
Pillbox (*beta*) (https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=Ebola%20Zaire%20Vaccine%20Live) (drug identification and images)
PubMed (https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=Ebola%20Zaire%20Vaccine%20Live%%5BAll+Fields%%5D) (scientific journals)
Safety-related Labeling Changes (https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges) (FDA/CDER)
ToxLine (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+toxline:%%22Ebola%20Zaire%20Vaccine%20Live%%22) (Toxicology Literature Online)

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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References

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3. Choi MJ, Cossaboom CM, Whitesell AN et al. Use of Ebola Vaccine: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Recomm Rep.* 2021; 70:1-12 [Web] (https://www.ncbi.nlm.nih.gov/pubmed/33417593?dopt=AbstractPlus)

4. US Centers for Disease Control and Prevention. Ebola vaccine: information for U.S. healthcare providers. From CDC website. Accessed 2021 Feb 25.[Web] (https://www.cdc.gov/vhf/ebola/clinicians/vaccine/index.html)