

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ERVEBO safely and effectively. See full prescribing information for ERVEBO.

ERVEBO® (Ebola Zaire Vaccine, Live) Suspension for intramuscular injection
Initial U.S. Approval: 2019

INDICATIONS AND USAGE

ERVEBO® is a vaccine indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older. (1)

Limitations of Use (1.1)

- The duration of protection conferred by ERVEBO is unknown.
- ERVEBO does not protect against other species of *Ebolavirus* or *Marburgvirus*.
- Effectiveness of the vaccine when administered concurrently with antiviral medication, immune globulin (IG), and/or blood or plasma transfusions is unknown.

DOSAGE AND ADMINISTRATION

- Administer a single 1 mL dose of ERVEBO intramuscularly. (2.1)

DOSAGE FORMS AND STRENGTHS

- 1 mL suspension for injection supplied as a single-dose vial. (3)

CONTRAINDICATIONS

- Severe allergic reaction (e.g., anaphylaxis) to any component of ERVEBO. (4)

WARNINGS AND PRECAUTIONS

- Anaphylaxis has been observed following administration of ERVEBO. Appropriate medical treatment and supervision must be available in case of anaphylactic event following the administration of ERVEBO. (5.1)
- Vaccinated individuals should continue to adhere to infection control practices to prevent *Zaire ebolavirus* infection and transmission. (5.2)
- Vaccine virus RNA has been detected in blood, saliva, urine, and fluid from skin vesicles of vaccinated adults; transmission of vaccine virus is a theoretical possibility. (5.4)

ADVERSE REACTIONS

- The most common injection-site adverse events were injection-site pain (70%), swelling (17%), and redness (12%). (6.1)
- The most common systemic adverse events reported following vaccination with ERVEBO were headache (37%), feverishness (34%), muscle pain (33%), fatigue (19%), joint pain (18%), nausea (8%), arthritis (5%), rash (4%) and abnormal sweating (3%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: XX/XXXX

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ERVEBO® is indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older.

1.1 Limitations of Use

- The duration of protection conferred by ERVEBO is unknown.
- ERVEBO does not protect against other species of *Ebolavirus* or *Marburgvirus*.
- Effectiveness of the vaccine when administered concurrently with antiviral medication, immune globulin (IG), and/or blood or plasma transfusions is unknown.

2 DOSAGE AND ADMINISTRATION

FOR INTRAMUSCULAR ADMINISTRATION ONLY.

2.1 Dosage

Administer 1 mL dose of ERVEBO.

2.2 Preparation

Thaw vial at room temperature until no visible ice is present. Do not thaw the vial in a refrigerator. Gently invert vial several times. The vaccine is a colorless to slightly brownish-yellow liquid with no particulates visible. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exist, discard the vial.

Use the vaccine immediately after thawing. If not used immediately, the vaccine may be stored for 4 hours at room temperature (up to 25°C; 77°F) protected from light. DO NOT REFREEZE [see *How Supplied/Storage and Handling (16)*].

Withdraw the 1 mL dose of vaccine from the vial using a sterile needle and sterile syringe.

2.3 Administration

Administer a 1 mL dose of ERVEBO intramuscularly, preferably in the deltoid area of the non-dominant arm. Discard unused portion.

3 DOSAGE FORMS AND STRENGTHS

ERVEBO is a suspension for injection supplied as a 1 mL dose in single-dose vials.

4 CONTRAINDICATIONS

Do not administer ERVEBO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including rice protein [see *Description (11)*].

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Among 17,415 subjects vaccinated with ERVEBO in clinical trials, there were two reports of anaphylaxis [see *Adverse Reactions (6.1)*]. Monitor individuals for signs and symptoms of hypersensitivity reactions following vaccination with ERVEBO. Appropriate medical treatment and supervision must be available in case of an anaphylactic event following the administration of ERVEBO.

5.2 Limitations of Vaccine Effectiveness

Vaccination with ERVEBO may not protect all individuals. Vaccinated individuals should continue to adhere to infection control practices to prevent *Zaire ebolavirus* infection and transmission.

5.3 Immunocompromised Individuals

The safety and effectiveness of ERVEBO have not been assessed in immunocompromised individuals. The effectiveness of ERVEBO in immunocompromised individuals may be diminished. The risk of vaccination with ERVEBO, a live virus vaccine, in immunocompromised individuals should be weighed against the risk of disease due to *Zaire ebolavirus*.

5.4 Transmission

Vaccine virus RNA has been detected by RT-PCR in blood, saliva, urine, and fluid from skin vesicles of vaccinated adults. Transmission of vaccine virus is a theoretical possibility [see *Pharmacokinetics (12.3)*].

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

The clinical development program for ERVEBO included clinical studies conducted in North America, Europe and Africa, in which 17,415 adults received a dose of ERVEBO. The number of subjects vaccinated with ERVEBO in double-blind, placebo-controlled trials was 1,712 and in open-label trials was 15,703.

In Study 1 (NCT02344407), conducted in Liberia (N=1,000), subjects were randomized 1:1 to receive ERVEBO or saline placebo. Subjects were assessed at Week 1 and Month 1 postvaccination for solicited local and systemic reactions. In a subset of subjects (n=201), joint symptoms and signs were also solicited during a Week 2 visit. Memory aids were not used and postvaccination temperatures were measured only at study visits. Unsolicited adverse events were collected through Month 1 postvaccination. The median age of subjects was 29 years, 63.6% were male and 100% were Black. Serious adverse events were monitored through 1 year postvaccination.

In Study 2 (NCT02503202), conducted in the United States, Canada and Spain (N=1,197), subjects were randomized to receive ERVEBO (n=1,061) or saline placebo (n=133). Subjects used a memory aid to record solicited local reactions from Days 1 to 5 postvaccination, and daily temperature measurements and solicited joint and skin events from Days 1 to 42 postvaccination. Unsolicited adverse reactions were collected through Day 42 postvaccination. The median age of subjects was 42 years; 46.8% were male; 67.9% were White, 29.2% were Black or African American, 1.4% were Multi-racial, 0.8% were Asian, 0.4% were American Indian or Alaska Native, and 0.3% were Native Hawaiian or Pacific Islander; 14.5% were Hispanic or Latino. Serious adverse events were monitored through 6 months postvaccination and a subset of subjects (n=511) were monitored through 24 months postvaccination.

In Study 3 (Pan African Clinical Trials Registry, PACTR201503001057193), an open-label cluster-randomized study conducted in the Republic of Guinea, 5,643 adult subjects received a dose of ERVEBO. The median age of vaccinated subjects was 37 years, 68% were male and 100% were Black. Serious adverse events were monitored through 84 days postvaccination.

In Study 4 (NCT02378753), a randomized open-label study conducted in Sierra Leone, 7,998 adult subjects received a dose of ERVEBO. The median age of subjects was 31 years, 63% were male; 99.8% were Black and 0.2% collectively were Multi-racial, Asian or White. Serious adverse events were monitored through 180 days postvaccination.

In Study 5 (Pan African Clinical Trials Registry, PACTR201503001057193), an open-label safety and immunogenicity trial conducted in vaccinated frontline workers in the Republic of Guinea, implemented as Part B of Study 3, 2,016 adult subjects received a dose of ERVEBO. The median age of vaccinated subjects was 30 years, 75% were male and 100% were Black. Serious adverse events were monitored through 85 days postvaccination.

Eight additional studies (NCT02269423, NCT02280408, NCT02374385, NCT02314923, NCT02287480, NCT02283099, NCT02296983) contributed to the assessment of serious adverse reactions.

Adverse Reactions

Table 1 presents the proportion of subjects reporting solicited adverse reactions in Study 1.

Table 1: Percentage of Subjects with Solicited Local and Systemic Adverse Reactions After Vaccination (Study 1)

	ERVEBO (%)	PLACEBO (%)
Injection-site reactions*	N= 500	N= 500
Injection site pain	34.0	11.2
Local reactions (redness/swelling)	1.8	0.8
Systemic adverse reactions†	N= 498	N= 499
Headache	36.9	23.2
Feverishness	34.3	14.8
Muscle pain	32.5	22.8
Fatigue	18.5	13.4
Nausea	8.0	4.4
Joint pain/tenderness‡	7.0	5.8
Rash	3.6	3.2
Abnormal sweating	3.2	2.6
Arthropathy (joint redness/warmth)‡	0.6	0.2
Joint swelling‡	0.4	0.4
Joint stiffness‡	0.4	0.2

* Adverse reactions were solicited at 30 minutes, Week 1 and Month 1 postvaccination.

† Adverse reactions were solicited at Week 1 and Month 1 postvaccination.

‡ In a subset of subjects (n=201), joint symptoms and signs were also solicited during a Week 2 visit.

In Study 1, 56.4% of subjects reported at least one of the solicited systemic adverse reactions listed in Table 1 within seven days after vaccination. With the exception of one subject who reported events of moderate intensity (causing greater than minimal interference with daily activity), all others reported events of mild intensity (causing no or minimal interference with daily activity).

Table 2 presents the proportion of subjects reporting solicited adverse reactions in Study 2.

Table 2: Percentage of Subjects with Solicited Local and Systemic Adverse Reactions After Vaccination (Study 2)

	ERVEBO (%)	Placebo (%)
Injection-site reactions*	N= 1051	N= 133
Injection-site pain	69.5	12.8
Injection-site swelling	16.5	3.0
Injection-site redness	11.9	1.5
Systemic adverse reactions†	N= 1051	N= 133
Joint pain	17.9	3.0
Arthritis (composite term)‡	4.7	0.0
Rash (composite term)§	3.8	1.5
Vesicular lesions¶	1.5	0.0

* Adverse reactions were solicited Days 1 to 5 postvaccination.

† Adverse reactions were solicited Day 1 through Day 42 postvaccination.

‡ Arthritis is a composite term that includes preferred terms of arthritis, monoarthritis, polyarthritis, osteoarthritis, joint swelling, or joint effusion.

§ Rash is a composite term that includes petechiae, purpura, rash, rash generalized, rash macular, rash papular and rash vesicular.

¶ Vesicular lesions include events reported as rash vesicular in the rash composite term and reported as blister.

In Study 2, 29 subjects (2.8%) reported injection-site pain of severe intensity. Severe arthritis (arthritis and joint swelling) was reported by 8 subjects (0.8%) and severe arthralgia was reported by 14 subjects (1.3%). In this study, severe events were defined as incapacitating with inability to work or do usual activity.

Unsolicited Adverse Reactions

In Study 2, the unsolicited adverse reaction of chills was reported in 7.3% of ERVEBO recipients compared to 0% of placebo recipients. Paresthesia was reported by 1.4% of ERVEBO recipients compared to 0% of those who received placebo in this study.

Arthralgia and Arthritis

Arthralgia was reported to occur in 7% to 40% of vaccine recipients in blinded, placebo-controlled studies. Arthralgia was generally reported in the first few days following vaccination, was of mild to moderate intensity, and resolved within one week after onset. Severe arthralgia, defined as preventing daily activity, was reported in up to 3% of subjects.

Arthritis (including events of arthritis, joint effusion, joint swelling, osteoarthritis, monoarthritis or polyarthritis) was reported to occur in 0% to 24% of subjects in blinded, placebo-controlled studies in which subjects received ERVEBO or a lower dose formulation, with all but one study reporting arthritis in <5% of subjects. Most occurrences of arthritis were reported within the first few weeks following vaccination, were of mild to moderate intensity, and resolved within several weeks after onset. In one study conducted in Switzerland (NCT02287480), 102 subjects received ERVEBO or a lower dose formulation. In this study, arthritis was reported to occur in 24% of subjects and severe arthritis, defined as preventing daily activity, in 12% of subjects. Joint effusion samples were obtained from three subjects and all three tested positive for vaccine virus RNA by RT-PCR. Of all 24 subjects with arthritis in this study, six subjects reported recurrent or prolonged joint symptoms lasting up to 2 years following vaccination, the longest follow-up period.

Rash

Rash was reported to occur after administration of ERVEBO in blinded, placebo-controlled studies, with all but one study reporting rash in <9% of subjects. In one study (NCT02287480), rash was reported to occur in 25% (n=4) of ERVEBO recipients and 7.7% (n=1) of placebo recipients. In this study, cutaneous vasculitis was reported in two subjects who received a lower dose formulation, neither of whom had evidence of systemic vasculitis. Vesicular fluid and skin biopsy samples taken from some subjects reporting rash have tested positive for vaccine virus RNA by RT-PCR.

Decreases in Lymphocytes and Neutrophils

White blood cell counts were assessed in 697 subjects who received ERVEBO. Decreases in lymphocytes were reported in up to 85% of subjects and decreases in neutrophils were reported in up to 43% of subjects. No associated infections were reported.

Serious Adverse Reactions

In 17,415 ERVEBO recipients, two serious adverse reactions of pyrexia were reported as vaccine-related. In addition, two serious adverse reactions of anaphylaxis were reported as vaccine-related. None of these serious adverse reactions were fatal.

7 DRUG INTERACTIONS

7.1 Interference with Laboratory Tests

Following vaccination with ERVEBO, 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 viremia, in the presence of vaccine-derived Ebola GP, and following antibody response to the vaccine [see *Pharmacokinetics* (12.3)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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

There are no adequate and well-controlled studies of ERVEBO in pregnant women, and human data available from clinical trials with ERVEBO 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*.

A developmental toxicity study has been performed in female rats administered a single human dose of ERVEBO on four occasions; twice prior to mating, once during gestation and once during lactation. This study revealed no evidence of harm to the fetus due to ERVEBO [see *Animal Data below*].

Clinical Considerations

Disease-associated Maternal and/or Embryo/Fetal Risk

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.

Fetal/Neonatal Adverse Reactions

The potential for transmission of the vaccine virus from mother to the fetus/neonate is unknown.

Data

Animal Data

In a developmental toxicity study, female rats received a single human dose of ERVEBO by intramuscular injection on four occasions: 28 days and 7 days prior to mating, gestation day 6 and lactation day 7. No adverse effects on pre-weaning development up to post-natal day 21 were observed. There were no vaccine-related fetal malformations or variations observed.

8.2 Lactation

Risk Summary

Human data are not available to assess the impact of ERVEBO on milk production, its presence in breast milk, or its effects on the breastfed child. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ERVEBO and any potential adverse effects on the breastfed child from ERVEBO or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

The safety and effectiveness of ERVEBO in individuals younger than 18 years of age have not been established.

8.5 Geriatric Use

Across the clinical development program, the total number of subjects ≥ 65 years of age who received ERVEBO was 542.

Clinical studies of ERVEBO did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger subjects.

11 DESCRIPTION

ERVEBO (Ebola Zaire Vaccine, Live) is a sterile suspension for intramuscular injection. ERVEBO is a live recombinant viral vaccine consisting of a vesicular stomatitis virus (VSV) backbone deleted for the VSV envelope glycoprotein and substituted with the envelope glycoprotein of the *Zaire ebolavirus* (Kikwit 1995 strain). The vaccine virus is grown in serum-free Vero cell cultures. The virus is harvested from the cell culture medium, purified, formulated with stabilizer solution, filled into vials and stored frozen. When thawed, ERVEBO is a colorless to slightly brownish-yellow liquid with no particulates visible.

Each 1 mL dose of ERVEBO contains a minimum of 72 million plaque forming units (pfu) of vaccine virus in a stabilizer solution containing 10 mM Tromethamine (Tris) and 2.5 mg/mL rice-derived recombinant human serum albumin. Each 1 mL dose may contain residual amounts of host cell DNA (≤ 10 ng) and benzonase (≤ 15 ng). The vaccine may contain trace amounts of rice protein. The product contains no preservatives.

The vaccine vial stopper is not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Immunization with ERVEBO 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.

12.3 Pharmacokinetics

Viremia

Vaccine viremia was evaluated in 186 subjects enrolled in seven clinical studies who were vaccinated with ERVEBO. Vaccine virus RNA was detected by RT-PCR in the plasma of most subjects from Day 1 to Day 7 postvaccination with one subject having a positive plasma RT-PCR result 14 days after vaccination.

Shedding

Shedding of vaccine virus into the urine or saliva was evaluated in 299 subjects enrolled in seven clinical studies who were vaccinated with ERVEBO or lower dose formulations. Vaccine virus RNA was detected by RT-PCR in the urine or saliva of some subjects at timepoints ranging from Day 1 through Day 14 postvaccination. In the two studies that assessed shedding at Day 28, no samples tested positive.

Vaccine virus RNA was detected by RT-PCR in vesicular fluid samples from some subjects. In one subject, a sample collected 20 days after vaccination tested positive for vaccine virus RNA by RT-PCR.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

ERVEBO has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility. ERVEBO administered to female rats had no effects on fertility [see *Use in Specific Populations (8.1)*].

14 CLINICAL STUDIES

14.1 Clinical Efficacy

Clinical efficacy of ERVEBO was assessed in Study 3.

Study 3 (Ring vaccination study) was an open-label, randomized cluster (ring) vaccination study conducted in the Republic of Guinea during the 2014 outbreak. Each cluster was composed of contacts and contacts of contacts of individuals with laboratory-confirmed Ebola virus disease (EVD). Clusters were randomized to receive either an "immediate" vaccination or a 21-day "delayed" vaccination. In the primary efficacy analysis, 3,537 subjects ≥ 18 years of age were considered contacts and contacts of contacts of an index case with laboratory-confirmed EVD. Of these, 2,108 were included in 51 immediate vaccination clusters, and 1,429 were included in 46 delayed vaccination clusters.

The median age of subjects in the primary efficacy analysis was 40 years. The majority were male, comprising 70.4% and 70.3% in the randomized immediate and delayed clusters, respectively.

In the primary efficacy analysis, the number of cases of laboratory-confirmed EVD in subjects vaccinated in immediate vaccination clusters was compared to the number of cases in subjects in delayed vaccination clusters. Cases of EVD that occurred between Day 10 and Day 31 post-randomization of the cluster were included in the analysis. Vaccine efficacy was 100% (95% CI: 63.5% to 100%); no cases of confirmed EVD were observed in the immediate vaccination clusters, and 10 confirmed cases of EVD were observed in a total of 4 delayed vaccination clusters between Day 10 and Day 31 post-randomization.

14.2 Clinical Immunogenicity

A measure of the immune response that confers protection against EVD is unknown. Four studies assessed antibody responses to ERVEBO (Study 1, Study 2, Study 4 and Study 5), including 477 subjects in Liberia, 506 subjects in Sierra Leone, 915 subjects in the US, Canada, and Spain (n= 865 US subjects) and 1,217 subjects in the Republic of Guinea. *Zaire ebolavirus* (Kikwit) GP-specific immunoglobulin G (IgG) was detected by enzyme linked immunosorbent assay (GP-ELISA). Vaccine virus neutralizing antibody was detected by a plaque reduction neutralization test (PRNT). Antibody responses among subjects in the study conducted in the US, Canada, and Spain were similar to those among subjects in the studies conducted in Liberia, Sierra Leone and the Republic of Guinea.

16 HOW SUPPLIED/STORAGE AND HANDLING

Carton of ten 1 mL single-dose vials. NDC 0006-4293-02

Store frozen at -80°C to -60°C (-112°F to -76°F). Store in the original carton to protect from light.

Do not thaw the vial in a refrigerator. Thaw the vial at room temperature until no visible ice is present. Use the vaccine immediately after thawing. If not used immediately, a thawed vial can be stored refrigerated at 2°C to 8°C (35.6°F to 46.4°F) for a total time of no more than 2 weeks and at room temperature (up to 25°C; 77°F) for a total time of no more than 4 hours. Protect from light. Do not re-freeze thawed vaccine.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Advise vaccine recipients of the following:

- ERVEBO has not been demonstrated to provide protection against disease caused by viruses other than *Zaire ebolavirus*. After vaccination with ERVEBO, individuals at risk should continue to protect themselves from exposure to *Zaire ebolavirus*.
- ERVEBO may not protect all vaccinated individuals.
- 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.

Instruct vaccine recipients to:

- Report any adverse reactions to their health care provider.
- Seek immediate medical attention if any signs or symptoms of a hypersensitivity reaction occur after vaccination [see *Contraindications (4)*].

Manufactured by: Merck Sharp & Dohme Corp., a subsidiary of
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For patent information: www.merck.com/product/patent/home.html

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