Introducing IXCHIQ®, the first and only vaccine for prevention against chikungunya in adults who are at increased risk of exposure to CHIKV[1]

Strong seroresponse rate[1,2]

98.9%
seroresponse rate at 28 days post vaccination*†

Established safety profile[1,2]

Demonstrated in adults 18 and older

Convenient single dose[1]

Administer as an intramuscular injection (approximately 0.5 mL after reconstitution)

Live attenuated[1]

A vaccine platform known for long-lasting immune response[3,4]

*In a double-blind, prospective, phase 3 study of 4,115 adults 18 years and older at 28 days post vaccination.[2]
†Seroresponse rate was defined as the proportion of participants with CHIKV neutralizing antibody titers ≥150 determined by $\mu PRNT_{50}$ for baseline negative participants 28 days post vaccination.[1,2]
CHIKV=chikungunya virus.

INDICATION

IXCHIQ is a vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV.

This indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory studies.

SELECTED SAFETY INFORMATION

Contraindications

Do not administer IXCHIQ to individuals who are immunodeficient or immunosuppressed due to disease or medical therapy (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised), or to individuals with a history of a severe allergic reaction to any component of the vaccine.

Warnings and Precautions

Appropriate medical treatment used to manage immediate allergic reactions must be available in the event an acute anaphylactic reaction occurs following administration of IXCHIQ.

Vaccination with IXCHIQ may cause severe or prolonged chikungunya-like adverse reactions. Severe chikungunya-like adverse reactions that prevented daily activity and/or required medical intervention occurred in 1.6% of 3,082 IXCHIQ recipients and no placebo recipients. Fourteen IXCHIQ recipients had prolonged (duration at least 30 days) chikungunya-like adverse reactions.

Potential for vertical transmission of vaccine virus and fetal/neonatal adverse reactions. Vertical transmission of wild-type CHIKV from pregnant individuals with viremia at delivery is common and can cause potentially fatal CHIKV disease in neonates. It is not known if the vaccine virus can be vertically transmitted and cause fetal or neonatal adverse reactions. Decisions to administer IXCHIQ during pregnancy should take into consideration the individual's risk of exposure to wild-type CHIKV, gestational age, and risks to the fetus or neonate from vertical transmission of wild-type CHIKV.

Syncope can occur with administration of IXCHIQ. Procedures should be in place to avoid injury from fainting.

IXCHIQ may not protect all individuals who receive the vaccine.

Please click here for additional Important Safety information and full Prescribing Information.

IXCHIQ®
(CHIKUNGUNYA VACCINE, LIVE)

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Prepare travelers with IXCHIQ

Pioneering the fight against chikungunya and its debilitating consequences

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For more information visit IXCHIQhcp.com

SELECTED SAFETY INFORMATION (cont'd)

Adverse Reactions

In clinical studies, the most common injection site reaction (>10%) was tenderness (11%). The most common systemic adverse reactions (>10%) were headache (32%), fatigue (29%), myalgia (24%), arthralgia (17%), fever (14%), and nausea (11%).

Use in Specific Populations

Pregnancy

There is a pregnancy registry to monitor outcomes in women exposed to IXCHIQ during pregnancy and it may be reached by contacting OXON Epidemiology at 1-855-417-6214. There are no adequate and well-controlled studies of IXCHIQ in pregnant individuals, and human data available from clinical trials with IXCHIQ are insufficient to establish the presence or absence of vaccine-associated risk during pregnancy.

To report SUSPECTED ADVERSE REACTIONS, contact Valneva at 1-844-349-4276 or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

Please click here for additional Important Safety information and full Prescribing Information.

References: 1. IXCHIQ. Prescribing information. Valneva USA Inc.; 2023. **2.** Schneider M, Narciso-Abraham M, Hadl S, et al. Safety and immunogenicity of a single-shot live-attenuated chikungunya vaccine: a double-blind, multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet*. 2023;401(10394):2138-2147. **3.** Minor PD. Live attenuated vaccines: historical successes and current challenges. *Virology*. 2015;479-480:379-392. **4.** Yadav DK, Yadav N, Khurana SMP. Vaccines: present status and applications. In: Verma AS, ed. *Animal Biotechnology: Models in Discovery and Translation*. Academic Press; 2014:491-508. **5.** Areas at risk for chikungunya. Centers for Disease Control and Prevention. Updated March 21, 2023. Accessed June 22, 2023. https://www.cdc.gov/chikungunya/geo/index.html

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