NEW

# IXCHIQ™

CHIKUNGUNYA VACCINE (LIVE, ATTENUATED)

INTRODUCING **IXCHIQ™**, THE FIRST AND ONLY VACCINE INDICATED IN THE PREVENTION OF CHIKUNGUNYA[1,2]*

# DISCOVER THE **POWER** OF IXCHIQ™

## INDICATION

IXCHIQ™ (chikungunya vaccine, live, attenuated) powder for solution for intramuscular injection is a live-attenuated vaccine, intended for active immunization in individuals 18 years and older for the prevention of disease caused by the chikungunya virus, as a single-dose immunization.[1]


# A PIONEER IN VACCINATION AGAINST CHIKUNGUNYA†

TO LEARN MORE ABOUT IXCHIQ™ VISIT **IXCHIQ.CA**

The landing page to this website will be open to the general public.

* Comparative clinical significance has not been established.
† IXCHIQ™ is the first and only vaccine indicated in the prevention of chikungunya.

valneva

## CHIKUNGUNYA IS A MOSQUITO-BORNE, VIRAL DISEASE CAUSED BY THE CHIKUNGUNYA VIRUS THAT CAN CAUSE **PERSISTENT ARTHRALGIAS** THAT CAN HAVE A SIGNIFICANT IMPACT ON PATIENT QUALITY OF LIFE.[4,5]

- The name "chikungunya" comes from the African Kimakonde language meaning "to become contorted" due to the stooped appearance of those with **chikungunya-related joint pain.**[4,6]
- Chikungunya virus is most commonly transmitted by *Aedes (Stegomyia) aegypti* and *Aedes (Stegomyia) albopictus* mosquitoes, primarily during daylight hours.[4]
- In infected individuals, the virus replicates, reaching high levels in their blood, allowing them to infect other mosquitoes and perpetuate the transmission cycle.[4]
- During epidemic periods, human beings serve as the primary reservoir hosts for the virus.[7]
- Chikungunya virus exists as a single serotype thought to confer life-long immunity in recovered individuals.[8]
- IXCHIQ™ does not treat chikungunya or its symptoms, or complications such as persistent arthralgias and impact on quality of life.

### COUNTRIES WITH OUTBREAKS OR EVIDENCE OF CHIKUNGUNYA VIRUS TRANSMISSION TO HUMANS DURING THE LAST 5 YEARS (AS OF MARCH 5, 2024)[3]


**CHIKUNGUNYA VIRUS OUTBREAK IN MALÉ AND HULHUMALÉ REGIONS OF MALDIVES** (AS OF MAY 28, 2024)[10,12]

- 389 cases reported
- The CDC issued at **Level 2** Health Alert Network Health Advisory to warn clinicians, travellers, and public health authorities to **practice enhanced precautions**.

Adapted from Centers for Disease Control and Prevention (2024).[3]

- Mosquito-borne chikungunya disease has become more frequent and widespread, with the virus having been identified in **over 110 countries** in Asia, Africa, Europe and the Americas.[4]
- **Over 75% of the world's population** is estimated to live in areas at risk of chikungunya. (according to 2015 estimates).[9]
- **Areas of greatest risk** for travellers are the Americas, parts of Africa, and Southeast Asia, with the following countries having reported the highest number of cases as of June 2024:[3,10]
  - Brazil (317,563)
  - Paraguay (3034)
  - Argentina (632)
  - Bolivia (346)
- Recent outbreaks in Argentina, Paraguay, and Uruguay support predictions that **climate change may be expanding the distribution of chikungunya virus.** This expansion increases the potential risk of epidemic transmission in highly populated temperate regions such as the United States, China, and continental Europe.[11]

## FOLLOWING ILLNESS, INDIVIDUALS WHO HAVE ACUTE INFECTIONS MAY PROGRESS TO CHRONIC DISEASE[5,13,14]

As many as 75% of those infected with chikungunya virus are symptomatic[14,15]

### Acute phase

The acute phase is most often characterized by a sudden onset of high fever and joint pain

Others symptoms may include headache, muscle pain, red eyes, nausea, vomiting, or rash[7,14]

| | |
|---|---|
| 3–7 days | symptoms typically begin after a bite from an infected mosquito[14] |
| 5–7 days | virus is present in the bloodstream[16] |
| 7–10 days | acute symptoms typically resolve[14] |

### Chronic phase


Results from a systematic review/meta-analysis show that **43% of chikungunya patients did not recover after 3 months (n=6532).**

**Chronic disease is characterized by joint pain, which can be debilitating and last for months to years.** [4,5,17,18]

Although studies report varying rates of long-term symptoms, all highlight the physical and potentially chronic burden of chikungunya in some patients:

- In one report, 173 individuals were identified with chikungunya virus, of whom **78.6% reported persisting musculoskeletal symptoms after 2 years.**[5,18,19]
- Further data showed that up to **72% of patients** with early significant improvement may relapse, the interval lasting from 1 week to **several years,** presenting with variable symptoms and affecting the same joints that had previously been affected.[18]
  - Chronic joint symptoms may include oligo- or polyarthralgia of variable intensity, usually symmetric, mainly in wrists, hands, ankles and knees, and are associated with morning stiffness and joint swelling.[18]

The **histopathological changes** in the synovial tissue **following chikungunya virus infection resemble those observed in patients with rheumatoid arthritis** or other chronic inflammatory joint diseases.[18]

**SEVERE JOINT PAIN FROM THE CHIKUNGUNYA VIRUS CAN LAST FOR MONTHS OR YEARS FOLLOWING INFECTION[4,5,17]**

## Chikungunya virus can cause **persistent arthralgias** that can have a **significant impact on patient quality of life**[18,20,21]

*"Chikungunya took a toll on my quality of life."*
– Kevin

- Joint and muscle pain
- Morning stiffness
- Emotional sequelae
- Psychosocial sequelae

**THERE ARE CURRENTLY NO SPECIFIC TREATMENTS AVAILABLE FOR CHIKUNGUNYA[4]**

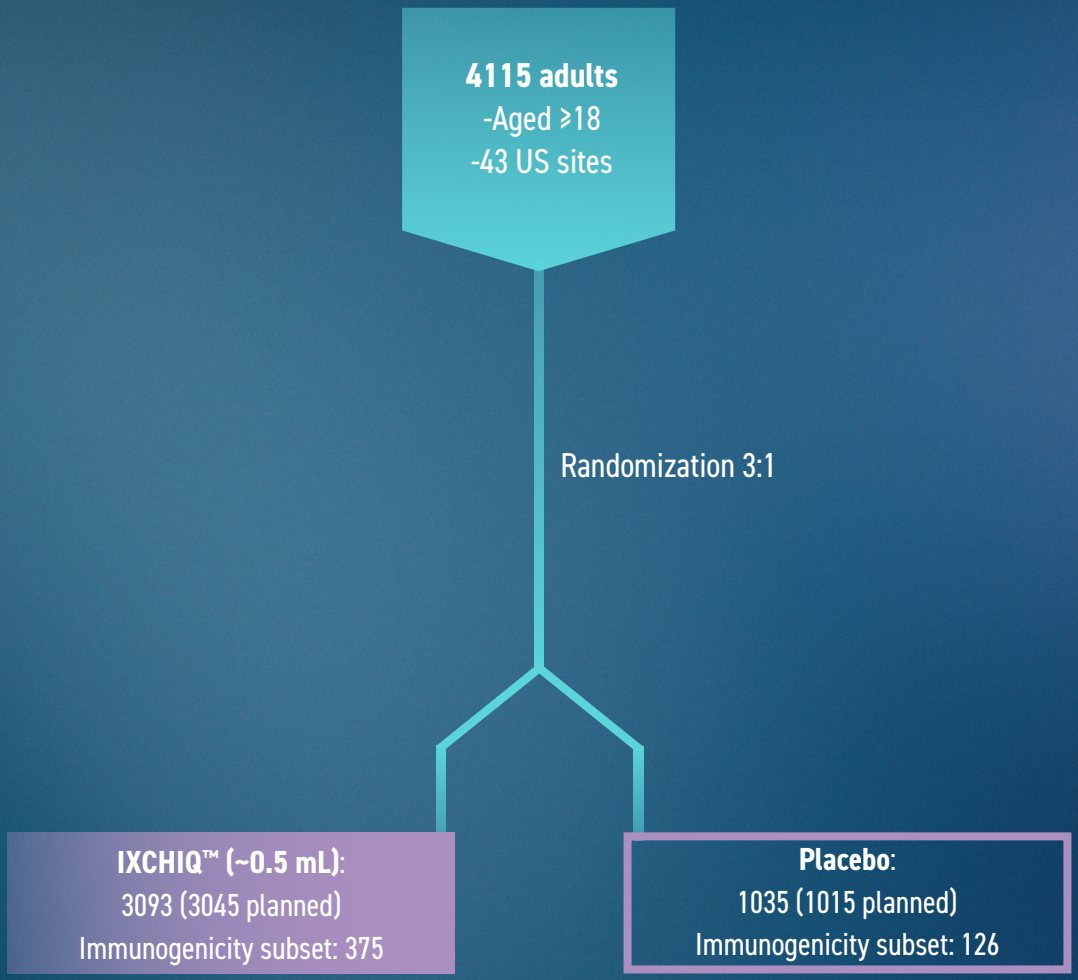
IXCHIQ™ does not treat chikungunya or its symptoms, or complications such as chronic musculoskeletal symptoms, including debilitating joint pain, joint swelling and morning stiffness, as well as as impact on quality of life, emotional and psychosocial sequelae.

Hypothetical patient.

CLINICAL DATA: STUDY DESIGN

## THE EFFICACY PROFILE OF IXCHIQ™ WAS EVALUATED IN A DOUBLE-BLIND, RANDOMIZED PLACEBO-CONTROLLED PHASE 3 TRIAL[1,22]

### Phase 3: A pivotal, multicenter, randomized, placebo-controlled, double-blind trial[1,22*]




Recruitment was stratified by age (18–64 years and ⩾65 years)

## IMMUNOGENICITY ENDPOINTS[1,22]

- Primary immunogenicity endpoint: Seroresponse rate (SRR), the surrogate immunogenicity endpoint of efficacy†
  - Defined as achieving a virus neutralizing antibody µPRNT50 titer ⩾150, which was considered to predict a clinical benefit, for baseline negative participants 28 days post-vaccination
- Secondary immunogenicity endpoint: The immune response as measured by chikungunya virus-specific neutralising antibody titres on Day 8, Day 29, Day 85, and at Month 6 post-vaccination as determined by µPRNT assay.

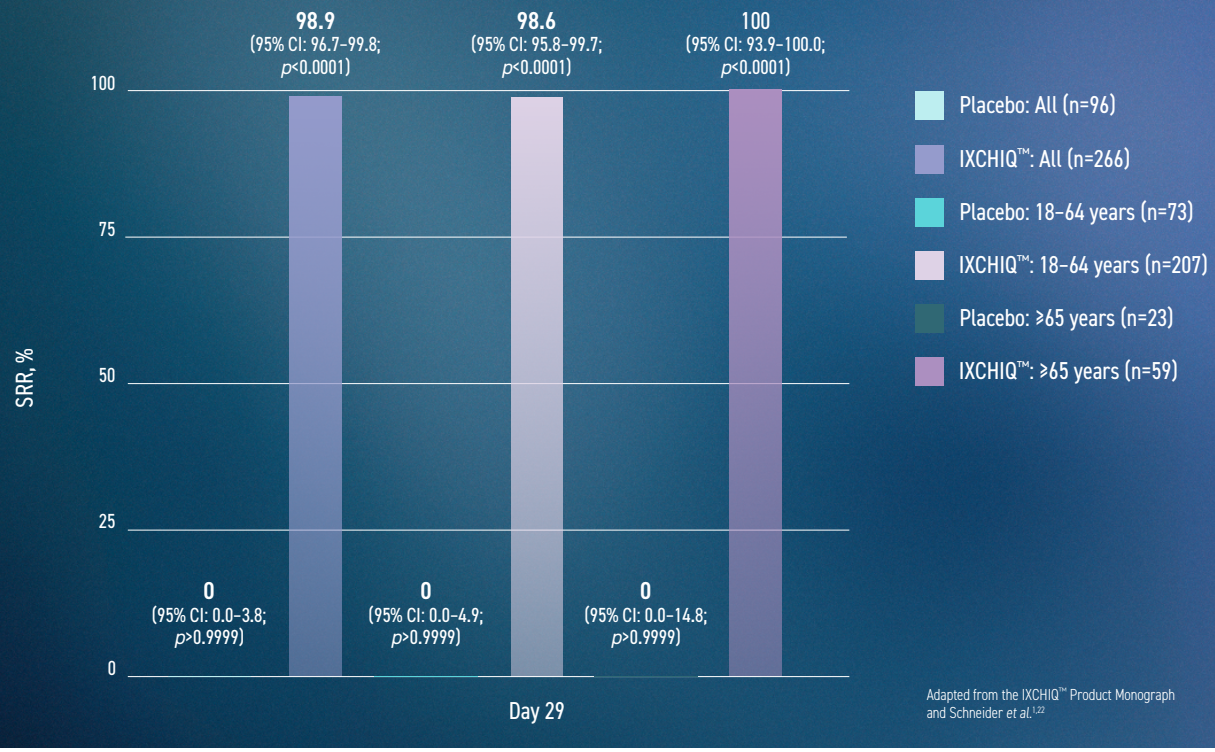
* Double-blind, randomized placebo controlled trial of 4115 adults (1864 M; 2251 F) aged 18–94. Study subjects received either IXCHIQ™ 1×10E4 $TCID_{50}$ per 0.5 mL or placebo (phosphate buffered saline) via intramuscular injection as a single dose with 6 month follow up. Healthy adult men and women were enrolled without prior known or suspected chikungunya virus infections and unlikely to become exposed to chikungunya virus during the study. Subjects with chronic illnesses or conditions that were stable and well-controlled on therapy for the past 6 months were eligible to participate in the clinical study. Immuno-compromised subjects were not eligible to participate in the clinical study.

† This is based on nonclinical data from a non-human primate pharmacology study showing that animals treated with immune sera from clinical samples collected in Study VLA1553-101 were protected against mild chikungunya virus (CHIKV) disease induced by challenge with a wild-type (WT) CHIKV strain. Pre-challenge neutralizing antibody titer level about 150 resulted in undetectable virus during 14 days after the challenge.

PRIMARY IMMUNOGENICITY ENDPOINT

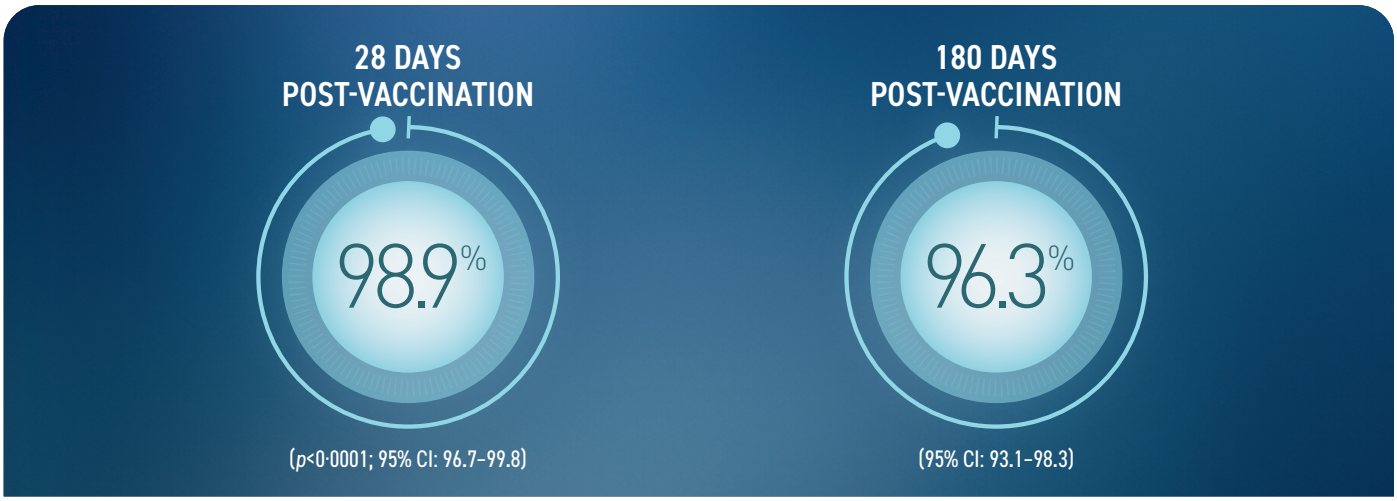
## STRONG SERORESPONSE RATES (SRRs) DEMONSTRATED IN A PIVOTAL STUDY[1,22*†‡]

### IXCHIQ™ induced a seroresponse in 98.9% of participants 28 days after a single dose[1,22‡§]




Adapted from the IXCHIQ™ Product Monograph and Schneider *et al.*[1,22]

### High SRRs were observed at 28 days post-vaccination and sustained at 180 days post-vaccination[1,22‡]

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† Percentage of participants with neutralizing antibody titers above the threshold of ≥150 determined by $\mu PRNT_{50}$ titer.

‡ Clinical significance unknown.

§ Success criterion: lower bound of the 95% CI for SRR >70%.

SRR: seroresponse rate; $TCID_{50}$: 50% tissue culture infectious dose; CI: confidence interval; μPRNT: micro plaque reduction neutralization test.

# IXCHIQ™ DEMONSTRATED A GENERALLY WELL-TOLERATED SAFETY PROFILE

The safety and tolerability profile of IXCHIQ™ was evaluated from 3 randomized, multicenter clinical studies.[1]*

The IXCHIQ™ safety data below was collected in 4115 participants from the main VLA1553-301 clinical trial, randomized 3:1 to receive IXCHIQ™ or placebo where 3082 healthy adults (18–88 years of age) received a single dose of IXCHIQ™ and 1033 received a placebo (Phosphate Buffered Saline). Participants were followed-up for safety for 6 months post-vaccination.[1]

### SOLICITED SYSTEMIC AND INJECTION SITE ADVERSE EVENTS WITHIN 10 DAYS AFTER A SINGLE VACCINATION (SAFETY POPULATION IN STUDY VLA1553-301)[1]

| AE category | Study VLA1553-301 | |
|---|---|---|
| | IXCHIQ™ (N=3082) | Placebo (N=1033) |
| Any solicited AEs | **53.0%** | **32.1%** |
| Solicited systemic AEs | **50.4%** | **27.0%** |
| Headache | 31.6% | 14.7% |
| Fatigue | 28.5% | 12.7% |
| Myalgia/muscle pain | 23.9% | 7.4% |
| Arthralgia/joint pain | 17.2% | 4.9% |
| Fever (≥38°C) | 13.5% | 0.9% |
| Nausea | 11.2% | 5.6% |
| Rash | 2.3% | 0.5% |
| Vomiting | 1.9% | 1.0% |
| **Solicited injection site AEs** | **15.0%** | **11.1%** |
| Tenderness | 10.6% | 8.1% |
| Pain | 6.2% | 3.7% |
| Erythema/Redness | 1.5% | 1.5% |
| Induration | 1.4% | 0.8% |
| Swelling | 0.7% | 0.8% |

Adapted from the IXCHIQ™ Product Monograph.[1]

All solicited injection site adverse reactions were graded as mild or moderate in severity, except for a single solicited injection site adverse reaction of pain graded as severe in the IXCHIQ™ group. Local and systemic adverse reactions resolved with a median duration of 2 days.[1]

## Chikungunya-like illness[1]

In study VLA1553-301, participants were monitored for a cluster of symptoms consistent with wild-type chikungunya infection. Chikungunya-like adverse reactions were defined as:

- fever (≥38 °C) and one or more of any of the following:
- arthralgia or arthritis, myalgia, headache, back pain, rash, lymphadenopathy, or certain neurological, cardiac or ocular symptoms that occurred with an onset within 30 days after vaccination, regardless of whether they occurred simultaneously or not.
- Severe chikungunya-like adverse reactions included symptoms that prevented daily activity and/or required medical intervention.

- Among Study VLA1553-301 participants, 11.7% in the IXCHIQ™ group (n= 3082) reported chikungunya-like adverse reactions, including 1.6% who reported severe chikungunya-like adverse reactions. 0.6% participants in the placebo group (n=1033) reported chikungunya-like adverse reactions, none of which was severe.
- The frequency of symptoms among participants (IXCHIQ™ N=361) with chikungunya-like adverse reactions was as follows: pyrexia (100%), headache (77.6%), fatigue (73.1%), myalgia (59.6%), arthralgia (44.0%), chills (8.0%), rash (6.1%), back pain (3.6%), lymphadenopathy (2.5%), dizziness (1.7%), pain (1.1%), paresthesia (0.8%), hyperhidrosis (0.6%), edema peripheral (0.6%), asthenia (0.3%), ataxia (0.3%), atrial fibrillation (0.3%), feeling abnormal (0.3%), hypoesthesia (0.3%), influenza-like illness (0.3%), neuropathy peripheral (0.3%), rash erythematous (0.3%), syncope (0.3%).
- The median onset of chikungunya-like reactions in IXCHIQ™ recipients was 3.0 days (range 0 to 10 days) after vaccination.
- The median duration of chikungunya-like reactions in IXCHIQ™ recipients was 4.0 days (range 1 day to at least 6 months) after vaccination.[1]
- 22 IXCHIQ™ recipients had prolonged chikungunya-like adverse reactions lasting longer than 14 days (median duration 33 days, range 15 days to at least 6 months) and 15 IXCHIQ™ recipients had chikungunya-like adverse reactions lasting longer than 28 days (median duration 94 days, range 29 days to at least 6 months).[1]

For more information on clinical trial adverse reactions, please refer to the IXCHIQ™ Product Monograph.

* Studies (VLA1553-301, VLA1553-302, and VLA1553-101) all conducted in North America in healthy adult participants 18 years of age and older. Study VLA1553-101 was done using an earlier formulation and was a supportive dose-escalation Phase I trial of IXCHIQ™ in 120 pa
double-blind placebo-controlled Phase III trial in 4115 participants who received IXCHIQ™ or placebo (phosphate buffered saline) as a single dose. Study VLA1553-302 was a supportive non-placebo-controlled Phase III trial investigating the consistency of three lots of IXCHIQ

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## IXCHIQ™ IS A CONVENIENT SINGLE-DOSE, LIVE-ATTENUATED VACCINE[1]

Administer the single dose as an intramuscular injection (approximately 0.5 mL after reconstitution).[1]

Reconstitute the live-attenuated vaccine only by adding the accompanying sterile water diluent into the vial containing the lyophilized IXCHIQ™ powder.[1]

**Storage and handling**

Store vial with lyophilized powder and diluent in a refrigerator at 2°C to 8°C (35°F to 46°F). Store in the original carton to protect from light.

DO NOT FREEZE.

Do not use the vaccine after the expiration date shown on the vial label.[1]

The reconstituted vaccine is a clear, colourless to slightly yellowish liquid solution.[1]

**Inspect** parenteral drug products visually for particulate matter and discoloration prior to administration and **do not** administer if either of the above conditions exists.[1]

After reconstitution, immediately administer IXCHIQ™ intramuscularly into the deltoid muscle. Discard reconstituted vaccine, if not used within 30 minutes.[1]

Any unused product or waste material should be disposed in accordance with local requirements.[1]

For complete instructions of use, please refer to the IXCHIQ™ Product Monograph.

## CONSIDER IXCHIQ™

### WHO IS AT RISK FOR CHIKUNGUNYA?[23-25]

Frequent traveller of chikungunya-endemic areas. Consider current and future travel plans as this will impact cumulative infection risk.

**Chikungunya in travellers returning to Canada**

- According to a Surveillance report from CanTravNet (surveillance data, 2006 to 2015) **the Caribbean was the most likely source region** for diagnoses of chikungunya.

People moving to chikungunya-endemic countries

Long-term travellers to endemic areas staying ≥6 months

Travellers to endemic areas with unplanned itineraries likely to be exposed to *Aedes* species mosquitoes

Short-term travellers to endemic areas with increased risk of being exposed to *Aedes* species mosquitoes based on planned activity and time of travel

Travellers to endemic areas visiting friends and relatives

rticipants. Study VLA1553-301 was the pivotal
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## SUMMARY

**IXCHIQ™: THE FIRST AND ONLY VACCINE INDICATED IN THE PREVENTION OF CHIKUNGUNYA.[1,2*]**

- IXCHIQ™ demonstrated strong seroresponse rate[1,22†]
  - 98.9% seroresponse rate (n/N=263/266; *p*<0·0001; 95% CI: 96.7–99.8) vs. 0% with placebo (n/N=0/96; *p*>0·9999; 95% CI: 0.0–3.8) at 28 days post-vaccination
- IXCHIQ™ demonstrated a well-established safety profile in adults 18 and older[1]

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- IXCHIQ™ is available as a convenient single-dose, live-attenuated vaccine
  - For complete instructions of use, please refer to the IXCHIQ™ Product Monograph.

## IXCHIQ™ SAFETY INFORMATION[1]

**Clinical use:**

**Pediatrics (<18 years)**: The safety and immunogenicity of IXCHIQ™ have not been established; therefore, Health Canada has not authorized an indication for pediatric use.

**Geriatrics (≥65 years)**: Clinical studies of IXCHIQ™ include participants 65 years of age and older and their data contribute to the overall assessment of safety and immunogenicity.

**Contraindications:**

- In individuals with a history of immunodeficiency (e.g., from hematologic and solid tumours, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised).
- In patients who are hypersensitive to this vaccine or to any ingredient in the formulation or component of the container.
- Pregnancy. Women of child-bearing potential should be advised to avoid pregnancy for one month following vaccination.

**Relevant warnings and precautions:**

- IXCHIQ™ is for intramuscular (IM) injection only.
- As with other vaccines, vaccination with IXCHIQ™ should be postponed in individuals suffering from an acute severe febrile illness or infection.
- Syncope (fainting) can occur following, or even before, any vaccination as a vasovagal response to the needle injection in the context of an anxiety-related reaction. It is important that procedures are in place to avoid injury from fainting.
- Vaccination with IXCHIQ™ may not protect all individuals. It is recommended to continue personal protection measures against mosquito bites after vaccination.
- Appropriate medical treatment and supervision must be available to manage immediate allergic reactions in the event an acute anaphylactic reaction occurs following administration of IXCHIQ™.
- No studies on the effects of IXCHIQ™ on the ability to drive and use machines have been performed. Exercise caution when driving or operating a vehicle or potentially dangerous machinery.
- As with other vaccines administered intramuscularly, IXCHIQ™ should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an IM administration to these individuals.
- Available data in adults with a history of immune-mediated or clinically relevant arthritis are not sufficient to determine the safety of IXCHIQ™, as this condition was an exclusion criterion for participation in clinical trials.
- Reproductive and developmental toxicology of IXCHIQ™ was conducted in a single pre- and post-natal developmental toxicity study in pregnant rats which did not identify significant adverse effects in female fertility or in fetal examination. No studies in male fertility were conducted.
- Available data in pregnant women are not sufficient to determine the safety of IXCHIQ™ regarding pregnancy, embryofetal development, parturition, and postnatal development.
- Vertical transmission of chikungunya virus (CHIKV) from mothers with viremia at delivery to their infants has been reported and can cause severe, potentially fatal neurological disease in neonates.
- Vaccine viremia can occur 3–7 days after vaccination and is resolved by day 14; the potential for transmission of the vaccine virus from mother to infant is unknown.
- Women who received IXCHIQ™ during pregnancy are encouraged to report any suspected exposure or adverse reactions to Valneva Canada, or ask their healthcare professional to do so.
- Potential for transmission of the vaccine virus from mother to infant through breastmilk is unknown. Precaution should be exercised.
- Any laboratory testing within 2 weeks post-vaccination with IXCHIQ™ may result in transient abnormalities in results, especially among hematology parameters.

**For more information:**

Please consult the Product Monograph at pdf.hres.ca/dpd_pm/00076049.PDF for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling us at 1-855-356-0831.

The drug identification number (DIN) for IXCHIQ™ is 02548984.

* Comparative clinical significance has not been established.
† Clinical significance unknown.

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NEW IXCHIQ™ CHIKUNGUNYA VACCINE (LIVE, ATTENUATED)

REVIEWED BY PAAB

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