IXCHIQ®

CHIKUNGUNYA VACCINE (LIVE, ATTENUATED)

IXCHIQ® IS 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 12 years and older for the prevention of disease caused by the chikungunya virus, as a single-dose immunization.[1]

Please refer to the Committee to Advise on Tropical Medicine and Travel (CATMAT) for guidance on the use of the travel-related vaccines in Canada, including IXCHIQ®.[1]

A PIONEER IN VACCINATION AGAINST CHIKUNGUNYA†

TO LEARN MORE ABOUT IXCHIQ® VISIT **IXCHIQHCP.CA**

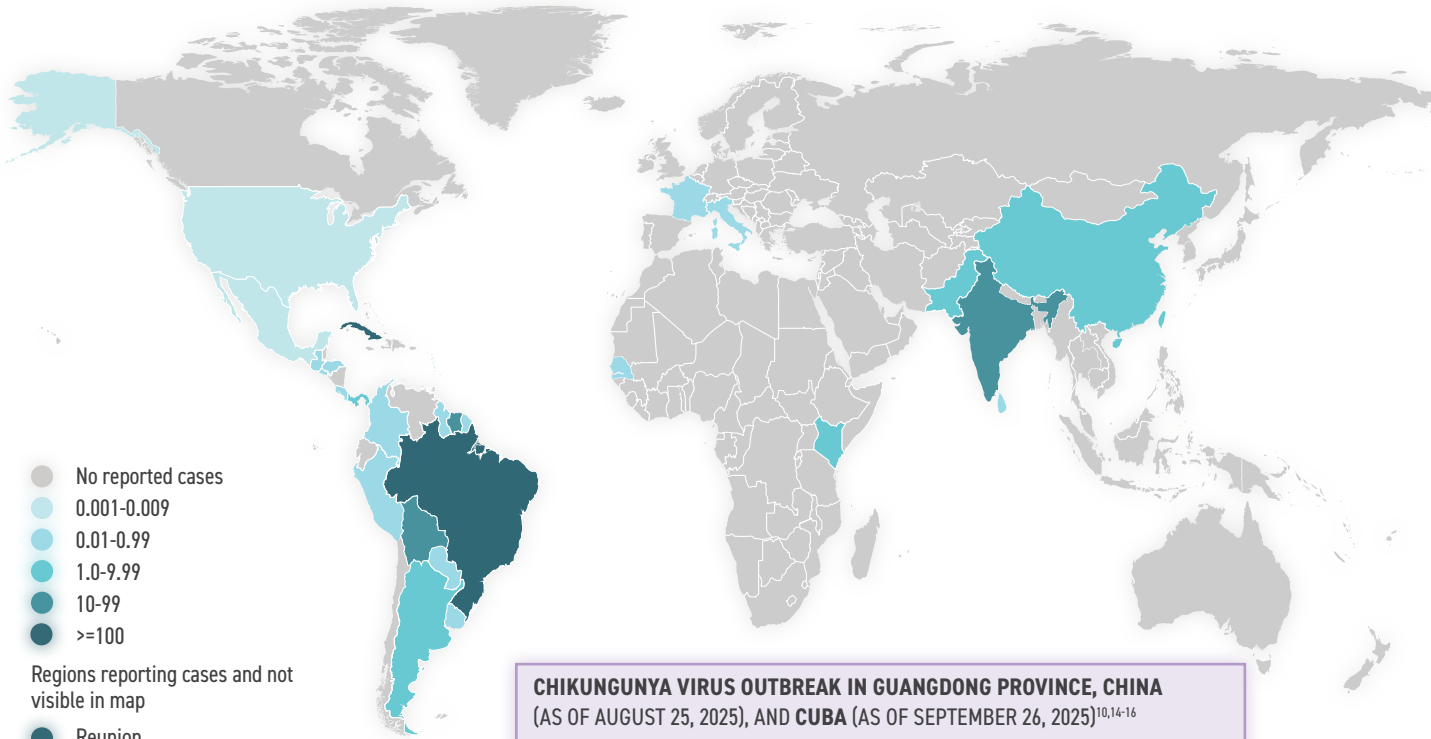
* Comparative clinical significance has not been established.
† IXCHIQ® is the first and only vaccine indicated in the prevention of chikungunya.

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.

12-MONTH CHIKUNGUNYA VIRUS DISEASE CASE NOTIFICATION RATE PER 100,000 POPULATION (FEBRUARY 2025 TO JANUARY 2026)



CHIKUNGUNYA VIRUS OUTBREAK IN GUANGDONG PROVINCE, CHINA (AS OF AUGUST 25, 2025), AND **CUBA** (AS OF SEPTEMBER 26, 2025)[10,14-16]

- As of January 3, 2026, a total of **51,217** cases have been reported in **Cuba**.
- As of September 27, 2025, a total of **16,452** locally transmitted cases have been reported in **Guangdong Province, China**.
- 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 the European Centre for Disease Prevention and Control.[9]

- Prior to 2025, current or previous autochthonous transmission of the chikungunya virus has been reported from **119 countries and territories**.[10]
  - **263,592 suspected** and **181,679 confirmed chikungunya cases** and **155 chikungunya-related deaths** have been reported globally (per data from January to September 2025).
  - IXCHIQ® is indicated for the prevention of disease caused by the chikungunya virus. It is not indicated for treating chikungunya or chikungunya related death and sequelae.
- **Over 75% of the world's population** is estimated to live in areas at risk of chikungunya. (according to 2015 estimates).[11]
- **As of mid-July 2025, the countries reporting the highest number of chikungunya cases are:**[12]
  - **Brazil (185,553)**
  - **Bolivia (4,721)**
  - **Argentina (2,836)**
  - **Peru (55)**
- 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.[13]

FOLLOWING ILLNESS, INDIVIDUALS WHO HAVE ACUTE INFECTIONS MAY PROGRESS TO CHRONIC DISEASE[5,17,18]

As many as 85% of those infected with chikungunya virus are symptomatic[18]

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[7,18]

3–7 days	symptoms typically begin after a bite from an infected mosquito[18]
5–7 days	virus is present in the bloodstream[19]
7–10 days	acute symptoms typically resolve[18]

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.[4,5,20,21]

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.**[5,21,22]
- 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.[21]
  - 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.[21]
- 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.[21]

Chikungunya virus can cause **persistent arthralgias** that can have a **significant impact on patient quality of life**[5,21,23,24]

"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.

Severe joint pain from the chikungunya virus can last for months or years following infection[4,5,20]

* Hypothetical patient.

SECONDARY IMMUNOGENICITY ENDPOINT

ANTIBODY PERSISTANCE DATA WAS REPORTED UP TO 2 YEARS POST-VACCINATION IN ADULTS[1*†]

- In **Study VLA1553-301**, the pivotal Phase III trial in adults (PP population; N=266 IXCHIQ®, N=96 placebo), Geometric Mean Titers (GMTs) of CHIKV-specific neutralizing antibodies were assessed by $\mu PRNT_{50}$ assay up to **6 months post-vaccination.***
- In **Study VLA1553-303**, the long-term follow-up of adults from VLA1553-301 (PP population; N=339), GMTs were evaluated annually by $\mu PRNT_{50}$ assay and antibody persistence data through 2 years post-vaccination was reported.†

GMT of serum CHIKV-specific neutralizing antibodies up to 2 years post-vaccination in adults

Adapted from the IXCHIQ® Product Monograph.[1]

GMT of serum CHIKV-specific neutralizing antibodies up to 6 months post-vaccination, as determined by µPRNT assay, in baseline seronegative adolescents was assessed in study VLA1553-321 (PP population)‡

	Study VLA1553-321 **ADOLESCENTS (12 to 17 years; baseline seronegative)**		
	Day 1	28 days post-vaccination	6 months post-vaccination
PLACEBO (N=42)	11.7 (10.46–13.17)	12.3 (9.63–15.79)	10.0 (10.00–10.00)
IXCHIQ® (N=251)	10.6 (10.31–10.89)	3,855.9 (3432.05–4331.98)	1,399.0 (1257.01–1556.98)

Adapted from the IXCHIQ® Product Monograph.[1]

* Study VLA1553-301: Multicenter, prospective, randomized, double-blinded, placebo-controlled pivotal clinical study with 6-month follow-up assessing the immunogenicity and safety in generally healthy individuals 18–94 years after vaccination with a single dose of IXCHIQ® (1×10^4 $TCID_{50}$ per 0.5 mL) or placebo (phosphate buffered saline, PBS) via intramuscular injection. Almost all participants were negative for CHIKV-specific neutralizing antibodies at baseline (99.9% in the VLA1553 group and 99.7% in the placebo group). 4,128 participants were randomized, allocated in approximately 3:1 ratio to VLA1553 arm (n=3,093) or placebo arm (n=1,035) and stratified by age.

† Study VLA1553-303: prospective, multicenter, open-label Phase 3b, single arm clinical trial evaluating antibody persistence and long-term safety (SAEs only) in 363 adult participants who had participated in Study VLA1553-301 and voluntarily agreed to be recruited into Study VLA1553-303. All participants were asked to visit the trial site on Day 180 of VLA1553-301 and then have annual follow-up visits for 10 years for immunogenicity sampling. SAEs were also assessed until Year 2 in all participants. Data are available up to Year 2.

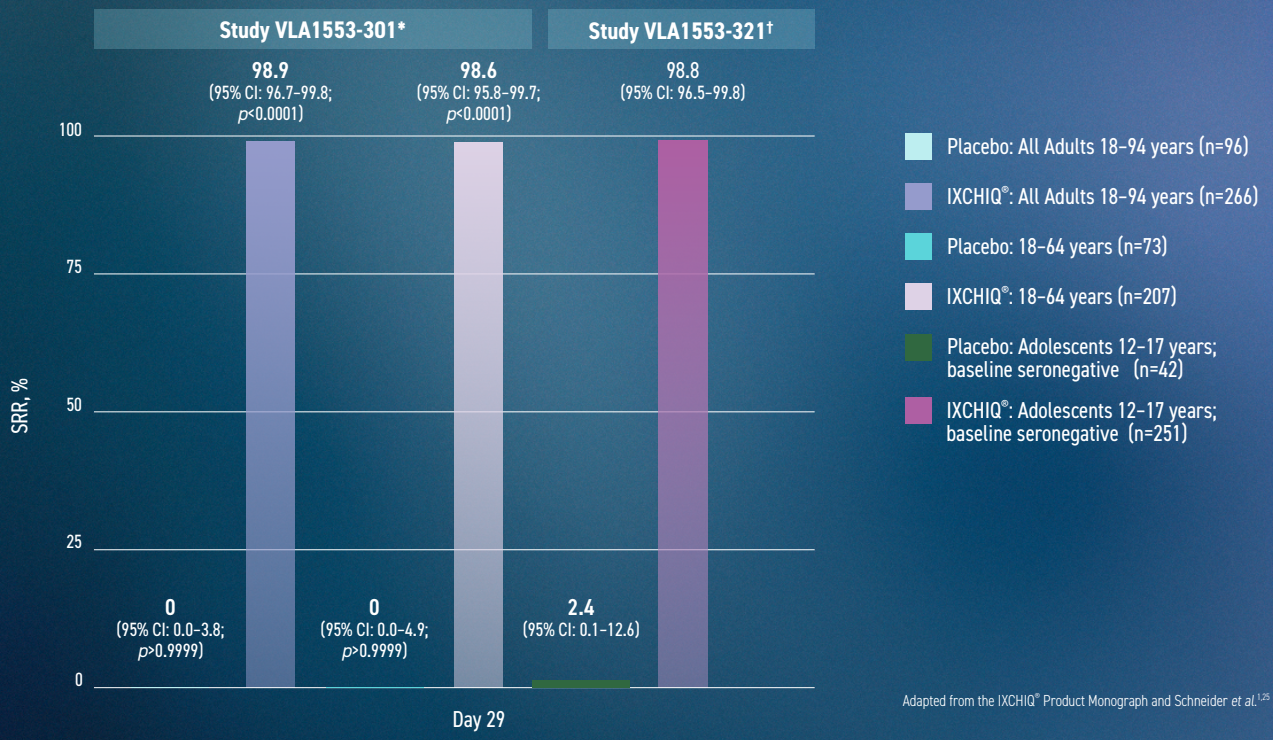
‡ Study VLA1553-321: Double-blind, randomized placebo controlled, multicenter, prospective trial of 754 adolescents (348 M; 406 F) aged 12–17. Study subjects received either IXCHIQ® 1×10^4 $TCID_{50}$ per 0.5 mL or placebo (phosphate buffered saline) via intramuscular injection as a single dose with 12 month follow up. 81.4% and 18.4% of the participants were seronegative and seropositive, respectively, for CHIKV-specific neutralizing antibodies at baseline. 754 participants were randomized in approximately 2:1 ratio to IXCHIQ® (n=502) or placebo (n=252) and stratified according to baseline serostatus for CHIKV-specific neutralizing antibodies. The first 384 of the randomized participants were included in the immunogenicity subset (IXCHIQ®-seronegative: n=268; placebo-seronegative: n=48; IXCHIQ®-seropositive: n=60; placebo-seropositive: n=8). 78 participants in the immunogenicity subset constituted the viremia subset (IXCHIQ®-seronegative: n=43; placebo-seronegative: n=20; IXCHIQ®-seropositive: n=9; placebo-seropositive: n=9).

CHIKV: chikungunya virus; SRR: seroresponse rate; CI: confidence interval.

PRIMARY IMMUNOGENICITY ENDPOINT

HIGH SERORESPONSE RATES (SRRS) DEMONSTRATED IN ADULTS* AND BASELINE SERONEGATIVE ADOLESCENTS† IN PIVOTAL CLINICAL TRIALS FOR IXCHIQ®[1,25]

SRRs 28 days post-vaccination‡§¶



Adapted from the IXCHIQ® Product Monograph and Schneider *et al.*[1,25]

Demonstrated SRRs at 1 and 2 years post-vaccination in adults (VLA1553-303)[1,25§**]

YEAR 1

99.5%

(183/184)
(95% CI: 97.0, 100.0)

YEAR 2

97.1%

(268/276)
(95% CI: 94.4, 98.7)

High SRRs were sustained up to 6 months post-vaccination in baseline seronegative adolescents (VLA1553-321)[1§]

6 MONTHS

99.1%

(95% CI: 96.9–99.9) vs. Placebo 0% (95% CI: 0.0, 9.0)

* Study VLA1553-301: Multicenter, prospective, randomized, double-blinded, placebo-controlled pivotal clinical study with 6-month follow-up assessing the immunogenicity and safety in generally healthy individuals 18–94 years after vaccination with a single dose of IXCHIQ® (1×10^4 $TCID_{50}$ per 0.5 mL) or placebo (phosphate buffered saline, PBS) via intramuscular injection. Almost all participants were negative for CHIKV-specific neutralizing antibodies at baseline (99.9% in the VLA1553 group and 99.7% in the placebo group). 4,128 participants were randomized, allocated in approximately 3:1 ratio to VLA1553 arm (n=3,093) or placebo arm (n=1,035) and stratified by age.

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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%.

** Study VLA1553-303: prospective, multicenter, open-label Phase 3b, single arm clinical trial evaluating antibody persistence and long-term safety (SAEs only) in 363 adult participants who had participated in Study VLA1553-301 and voluntarily agreed to be recruited into Study VLA1553-303. All participants were asked to visit the trial site on Day 180 of VLA1553-301 and then have annual follow-up visits for 10 years for immunogenicity sampling. SAEs were also assessed until Year 2 in all participants. Data are available up to Year 2.

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

Available post-marketing data suggest that individuals ⩾65 years of age who are medically frail with multiple chronic medical conditions may have increased risk for serious and life-threatening adverse reactions following recent vaccination with IXCHIQ®. **IXCHIQ® should only be given when there is a significant risk of acquiring chikungunya infection, and after careful consideration of the potential risks and benefits.**

THE FOLLOWING ARE THE MOST COMMON SOLICITED SYSTEMIC AND INJECTION SITE ADVERSE REACTIONS WITHIN 10 DAYS REPORTED IN ADULT AND ADOLESCENT SAFETY POPULATIONS.

	Study VLA1553-301 **ADULTS**, % (N=3082)	Study VLA1553-321 **ADOLESCENTS, %** (seronegative; N=408)
Adverse Event		
Headache	31.6%	54.7%
Myalgia	23.9%	28.7%
Fever (⩾38°C adults, ⩾37.8°C adolescents)	13.5%	28.2%
Fatigue	28.5%	24.8%
Nausea	11.2%	17.4%
Arthralgia	17.2%	14.5%
Injection site reactions		
Tenderness	10.6%	21.6%
Pain	6.2%	18.6%

Adapted from the IXCHIQ® Product Monograph.[1]

- The majority of solicited systemic adverse reactions were of **mild** to **moderate intensity** (>95% in adults; >94% in baseline seronegative adolescents).
- In adults, the median day of onset was Day 2 after vaccination for local injection site adverse reactions and Day 5 after vaccination for systemic adverse reactions.

- Solicited systemic and local adverse reactions **resolved with a median duration of 2 days in adults and 1 to 2 days in baseline seronegative adolescents.**

Chikungunya-like illness[1]

Participants were monitored for a cluster of symptoms consistent with typical symptoms of wild-type chikungunya infection (chikungunya-like adverse reactions), defined as:

- fever (⩾38 °C in Study VLA1553-301 or ⩾37.8 °C in Study VLA1553-321) and one or more of any of the following:
- arthralgia or arthritis, myalgia, headache, back pain (only in Study VLA1553-301), rash or certain skin symptoms, lymphadenopathy (only in Study VLA1553-301), or certain neurological, cardiac (only in Study VLA1553-301) 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.

VLA1553-301 **Adult participants (⩾18 years)**	VLA1553-321 **Adolescent participants (12 to 17 years; baseline seronegative)**
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.	27.0% in the IXCHIQ® group (n=408) reported chikungunya-like adverse reactions, including 4.2% who reported severe chikungunya-like adverse reactions. 3.9% baseline seronegative participants in the placebo group (n=206) reported chikungunya-like adverse reactions, none of which was severe.

Post-marketing data

- During a vaccination campaign to address an outbreak in Reunion Island early in 2025, **three deaths** occurred within two weeks post-vaccination among **frail elderly men with multiple comorbidities** (advanced neurological disorders and respiratory illness, pneumonia), due to medical decompensation (88 and 77 years of age) or confirmed encephalitis (84 years of age); **one death** was assessed as probably related to IXCHIQ® vaccination by the local health authority. **No deaths were reported** in individuals vaccinated for the purpose of international travel.

For more information about the safety and tolerability profile of IXCHIQ®, including post-market adverse reactions, please consult the Product Monograph.

* In adults 18 years of age and older, the safety and tolerability profile of IXCHIQ® was evaluated in baseline seronegative adults in the study VLA1553-301. Safety data collected in 4,115 participants from the main VLA1553-301 clinical trial, randomized 3:1 to receive IXCHIQ® o received a single intramuscular dose (1×10^4 $TCID_{50}$) of IXCHIQ® and 1,033 received placebo. Participants were followed-up for safety for 6 months post-vaccination.

† In adolescents aged 12 to 17 years, the safety and tolerability profile of IXCHIQ® was evaluated in a randomized, double-blind, placebo-controlled phase 3 trial. Study VLA1553-321 enrolled 754 participants who received either a single intramuscular dose (1×10^4 $TCID_{50}$) of IXC 18.4% of participants had pre-existing antibodies against CHIKV, while 81.4% were CHIKV-naïve. Randomization was stratified by CHIKV baseline serostatus.

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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), **at least 4 weeks** before patient departure.[1]

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

A needle (22-25G) with appropriate length of preferably at least 40mm (1 1/2") should be used for reconstitution of the vaccine.[1]

For complete dosing and administration information, including storage and handling, please refer to the IXCHIQ® Product Monograph or scan the QR code to access the information on IXCHIQHCP.ca

CONSIDER IXCHIQ® AT LEAST 4 WEEKS BEFORE DEPARTURE TO HELP PROTECT YOUR TRAVELLING PATIENTS.

CONSIDER VACCINATION

For your adult and adolescent travellers when there is a significant risk of acquiring chikungunya infection and after careful consideration of the potential risks and benefits

Travellers to endemic areas with unplanned itineraries and length of stay[26,27]

MARCUS

27-year-old freelance graphic designer

Often takes spontaneous trips with friends and is currently planning last-minute island-hopping in the Caribbean. Because of the unplanned nature of his itineraries, he is more likely to be exposed to *Aedes* mosquitoes in endemic areas.

Short-term travellers to endemic areas especially when their planned activities and time of travel increase the likelihood of encountering the disease[26,28]

ALINA

35-year-old technology project manager

Preparing for a two-week work trip to Guangdong, China, during an active chikungunya outbreak. As a short-term traveller to an outbreak area, her business trip places her at heightened risk of exposure to mosquitoes carrying the chikungunya virus.

Travellers to endemic areas visiting friends and relatives[26,27]

THE CLARKE FAMILY

Parents with their 16-year-old daughter

Travel annually to India to visit relatives. Their trips often include extended stays in rural and suburban areas, where visiting friends and relatives can increase their risk of exposure to *Aedes* mosquitoes and chikungunya infection.

Frequent travellers to destinations at risk of chikungunya[26,28]

DAVID

42-year-old international consultant and avid traveller

Travels frequently throughout the year, combining work commitments with short vacations. Since some of his destinations are in chikungunya-endemic regions, his pattern of frequent travel increases his risk of exposure to mosquitoes carrying the virus.

For illustrative purpose only. Does not depict actual patient cases.

r PBS (placebo). A total of 3,082 healthy adults 18 through 88 years of age

HIQ® (n=502) or placebo (PBS; n=252), with a follow-up period of 6 months.

pidemiology-update_11june2025.pdf. Accessed August 26, 2025. **4.** World Health Organization. Chikungunya. Published April 14, 2025. Available at: https://www.who.int/news-room/fact-sheets/detail/chikungunya. Accessed August 26, 2025. **5.** Craig J, *et al.* Diagnostic ogy, clinical syndrome, pathogenesis and therapy. *Antivir Res.* 2013 ;99(3):345–370. **8.** Sahadeo N, *et al.* Molecular Characterisation of chikungunya virus infections in Trinidad and comparison of clinical and laboratory features with dengue and other acute febrile cases. ons-data/12-month-chikungunya-virus-disease-case-notification-rate-100-000-population-9. Accessed March 11, 2026. **10.** World Health Organization. Chikungunya virus disease- Global situation. Available at: https://www.who.int/emergencies/disease-outbreak-news/ kungunya worldwide overview. Available at: https://www.ecdc.europa.eu/en/chikungunya-monthly. Accessed August 26, 2025. **13.** de Souza, *et al.* Pathophysiology of chikungunya virus infection associated with fatal outcomes. *Cell Host Microbe.* 2024; 32:606–622. **14.** Centers c.gov/travel/notices/level2/chikungunya-cuba. Accessed November 3, 2025. **16.** Pan American Health Organization. Chikungunya: analysis by country. Available at: https://www.paho.org/en/arbo-portal/chikungunya-data-and-analysis/chikungunya-analysis-country. 25. Available at:. https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/chikungunya. **19.** Silva L, Dermody T. Chikungunya virus: epidemiology, replication, disease mechanisms, and prospective intervention strategies. *J Clin Invest.* 2017;127(3):737–749. er. Part 1 – Diagnosis and special situations. *Rev Bras Reumatol.* 2017;57(S2):S421–S437. **22.** Essackjee K, *et al.* Prevalence of and risk factors for chronic arthralgia and rheumatoid-like polyarthritis more than 2 years after infection with chikungunya virus. *Postgrad Med J.* 08. Accessed July 25, 2024. Available at: https://iris.who.int/bitstream/handle/10665/205178/B3234.pdf?sequence=1. **25.** Schneider M., *et al.* Safety and immunogenicity of a single-shot live-attenuated chikungunya vaccine: A double-blind, multicentre, randomised, gunya/media/pdfs/2024/05/Chikungunya-vaccine-risk-factors-508.pdf. **27.** Boggild AK. *et al.* Chikungunya in travellers returning to Canada: Surveillance report from CanTravNet surveillance data, 2006 to 2015. *J Assoc Med Microbiol Infect Dis Can.* 2016;1(3):1–16.

SUMMARY

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

- IXCHIQ® demonstrated strong seroresponse rate[1,25†]
  - **Study VLA1553-301 in adult participants:** 98.9% seroresponse rate (n/N=263/266; $p<0{\cdot}0001$; 95% CI: 96.7–99.8) vs. 0% with placebo (n/N=0/96; $p>0{\cdot}9999$; 95% CI: 0.0–3.8) at 28 days post-vaccination
  - **Study VLA1553-321 in adolescent participants (baseline seronegative):** 98.8% seroresponse rate (n/N=248/251; 95% CI: 96.5–99.8) vs. 2.4% with placebo (n/N=1/42; 95% CI: 0.1–12.6) at 28 days post-vaccination
- IXCHIQ® demonstrated a well-established safety profile in adults and adolescents (baseline seronegative) 12 years and older[1]
- IXCHIQ® is a live-attenuated vaccine available as a convenient single-dose immunization to be administered at least 4 weeks before travel[1]
  - For complete instructions of use, please refer to the IXCHIQ® Product Monograph.

IXCHIQ® SAFETY INFORMATION[1]

Clinical use:

Pediatrics (<12 years): The safety and immunogenicity of IXCHIQ® have not been established; therefore, Health Canada has not authorized an indication for individuals under 12 years of age.

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:

- Individuals with current or suspected immunodeficiency or immunosuppression (e.g., from malignancies such as hematologic cancers and solid tumors, recent chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy for chronic conditions such as autoimmune disorders or organ transplants, or poorly managed HIV infection with immunocompromised state).
- 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.

Most serious warnings and precautions:

Risk for individuals ≥65 years of age: Available post-marketing data suggest that individuals 65 years of age and older who are medically frail with multiple chronic medical conditions may have an increased risk for serious and life-threatening adverse reactions following recent vaccination with IXCHIQ®.

Relevant warnings and precautions:

- IXCHIQ® is for intramuscular (IM) injection only.
- IXCHIQ® should only be given when there is a significant risk of acquiring chikungunya infection and after careful consideration of the potential risks and benefits.
- **Serious adverse reactions following vaccination with IXCHIQ® were most commonly reported in medically frail individuals with advanced chronic diseases, individuals at older age (i.e., ≥65 years of age, especially ≥75 years of age), and those with a high risk of having an undiagnosed immunocompromised condition (post-market data).**
- **Severe reactogenicity or chikungunya-like adverse reactions in medically frail individuals with chronic diseases may lead to deterioration of general condition including malaise and decreased appetite, exacerbation of preexisting diseases, confusional state, encephalopathy, or encephalitis, leading to falls, hospitalization and death.**
- 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, however, some adverse effects may temporarily affect the ability to drive or use machines. 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 and adolescents 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.
- **Additional cases of prolonged chikungunya-like arthralgia reported (range: few weeks – over 5 months) with some requiring follow-up with rheumatology (post-market data).**
- **Encephalitis and encephalopathy (including with fatal outcome) have been reported in individuals 74 years and older with multiple comorbidities (post-market data).**
- Vaccinees should be instructed to promptly seek medical attention if experiencing signs or symptoms suggestive of severe reactogenicity, severe chikungunya-like adverse events, prolonged arthralgia or a neurological disorder, post-vaccination.
- 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.
- There are no data on the safety and immunogenicity following concomitant administration of IXCHIQ® with other vaccines. During post-marketing use, some severe ICSR cases involved co-administration with other vaccines. Administration of immune globulins, blood or plasma transfusions 3 months before or up to 1 month after IXCHIQ® administration may interfere with the expected immune response.
- 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/00083177.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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IXCHIQ® CHIKUNGUNYA VACCINE (LIVE, ATTENUATED)

REVIEWED BY PAAB

valneva