



IXCHIQ/ chikungunya patient information



*In a double-blind, prospective, phase 3 study of 4,115 adults 18 years and older at 28 days post vaccination.

What is IXCHIQ used for?

IXCHIQ is a vaccine for use in individuals 18 years of age and older to help protect against chikungunya virus disease.

- You should still protect yourself from mosquito bites even if you have received the IXCHIQ vaccine
- IXCHIQ may not fully protect everyone who gets the vaccine
- IXCHIQ does not protect against other diseases transmitted by mosquitoes

This vaccine is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory studies.

You should not get IXCHIQ if you:

- Have a weakened immune system due to certain conditions or therapy
- Have ever had a severe allergic reaction to any of the ingredients in the vaccine

IXCHIQ is not approved for use in children below the age of 18 years.

Please see full Important Safety Information on page 5 and full Prescribing Information.



1 Why get vaccinated?

Chikungunya vaccine can help protect against chikungunya disease.

Chikungunya is a disease transmitted by mosquitoes spreading the chikungunya virus, CHIKV, which is found in the subtropical regions of the Americas, Africa, Southeast Asia, India, and the Pacific Region. As of late 2020, outbreaks of chikungunya in the Americas have resulted in an estimated 3 million cases. Since 2012, the virus has moved into European territories, with 13 EU countries reporting 2,616 travel-related chikungunya cases.

All travelers to endemic regions are at risk for infection. Health authorities warn of a high risk for chikungunya virus as the mosquitoes that spread the disease begin to establish in new areas. The impact is likely the greatest for populations naive to the virus, such as travelers who have returned from endemic areas. It is recommended that travelers prevent mosquito bites by wearing repellent for 3 weeks after their trip.

The majority of CHIKV-infected people (up to 97%) develop symptoms characterized by acute onset of fever and severe pain in multiple joints. Acute symptoms typically resolve within 7 to 10 days, but some symptoms, in particular the joint pain associated with chikungunya, is often debilitating and may last for months to years in some people (up to 43%). "Chikungunya" means "to become contorted" in the African Kimakonde language, describing the effects of chikungunya-related persistent joint pain.

There is no specific treatment for chikungunya. The clinical management includes addressing fever and joint pain with anti-inflammatory agents and painkillers such as ibuprofen and acetaminophen, drinking plenty of fluids, and general rest.

2 Chikungunya vaccine

IXCHIQ® (chikungunya vaccine, live) is a vaccine approved 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.

Data from clinical trials showed that IXCHIQ stimulated neutralizing antibodies in 98.9% of adults at 28 days post vaccination, with sustained antibody titers up to 6 months.

In clinical studies, the most common solicited injection site adverse reaction (>10%) was tenderness (10.6%). The most common solicited systemic adverse reactions (>20%) were headache (31.6%), fatigue (28.5%), and muscle pain (23.9%). In some cases, joint pain (17.2%), fever (13.5%), nausea (11.2%), rash (2.3%), and vomiting (1.9%) may occur.

Like all vaccines, IXCHIQ may not protect everyone who gets the vaccine. You should still protect yourself from mosquito bites even if you have received the IXCHIQ vaccine. Follow precautions to reduce exposure to mosquito bites (adequate clothing, use of repellents, mosquito nets).

Please see full Important Safety Information on page 5 and full [Prescribing Information](#).

3 If you are concerned about the risks of chikungunya, talk to your healthcare provider

It is very important to tell your healthcare provider if you:

- Have had an allergic reaction to any ingredient of IXCHIQ
- Have a bleeding disorder or are on a blood thinner
- Have a weakened immune system due to a condition or therapy
- Are or may be pregnant or are breastfeeding
- Currently have any illness with a fever of more than 38.0°C (100.4°F)
- Take any medicines, even those you can buy over the counter

You should not get IXCHIQ if you:

- Have a weakened immune system due to certain conditions or therapy
- Have ever had a severe allergic reaction to any of the ingredients in the vaccine

IXCHIQ is not approved for use in children below the age of 18 years.

4 Common side effects

The most common side effects are headache, fatigue, and muscle pain. Joint pain, fever, nausea, rash, and vomiting may also occur. In clinical studies, these side effects resolved with a median duration of 2 days.

The most common injection site adverse reaction is tenderness. Pain, redness, hardening, and swelling may also occur. In clinical studies, these reactions resolved with a median duration of 2 days.

Syncope (fainting) may occur in association with administration of injectable vaccines, including IXCHIQ.



5 What if there is a serious problem?

Contact your healthcare provider right away if you get any symptoms after receiving IXCHIQ that concern you.

Tell your healthcare provider if you have any of the following problems because these may be signs of an allergic reaction: difficulty breathing, hoarseness, wheezing, hives, dizziness, weakness, or fast heartbeat.

To report suspected adverse reactions, contact Valneva USA Inc. at **1-844-349-4276** or VAERS at **1-800-822-7967** or <http://vaers.hhs.gov>.

6 How can I learn more?

- Ask your healthcare provider
- Consult current national and international advisories regarding prevalence of chikungunya virus in specific locations
- Visit the US Centers for Disease Control and Prevention (CDC) and the Pan American Health Organization (PAHO)/World Health Organization (WHO) websites:

[CDC chikungunya website](#)

[PAHO/WHO chikungunya fact sheet](#)

Please see full Important Safety Information on page 5 and full [Prescribing Information](#).



IXCHIQ® (chikungunya vaccine, live) Solution for Intramuscular Injection

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You should not get IXCHIQ if you:

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- Have ever had a severe allergic reaction to any of the ingredients in the vaccine

IXCHIQ is not approved for use in children below the age of 18 years.

What warnings should I know about IXCHIQ?

- IXCHIQ can cause allergic reactions. Tell your healthcare provider immediately if you experience difficulty breathing, hoarseness, wheezing, hives, dizziness, weakness, or fast heartbeat
- IXCHIQ may cause severe or prolonged chikungunya-like side effects. Tell your healthcare provider about any side effects you experience

What warnings should I know about IXCHIQ? (cont'd)

- Chikungunya virus can be passed from a pregnant individual to an unborn baby. It is not known if the vaccine virus can be transmitted from a pregnant individual to the fetus or newborn and cause adverse reactions
- Fainting can occur with administration of IXCHIQ
- Vaccination with IXCHIQ may not protect all who receive the vaccine. Continue to use methods to protect against mosquito bites after vaccination

What should I tell my healthcare provider?

It is very important to tell your healthcare provider if you:

- Have had an allergic reaction to any ingredient of IXCHIQ
- Have a bleeding disorder or are on a blood thinner
- Have a weakened immune system due to a condition or therapy
- Are or may be pregnant or are breastfeeding
- Currently have any illness with a fever of more than 38.0°C (100.4°F)
- Take any medicines, even those you can buy over the counter

What are the side effects of IXCHIQ?

The most common side effects are headache, fatigue, muscle pain, joint pain, fever, tenderness at the injection site, and nausea.

You are encouraged to report suspected adverse reactions to Valneva at 1-844-349-4276 or VAERS at 1-800-822-7969 or <http://vaers.hhs.gov>.

For more information on IXCHIQ® (chikungunya vaccine, live), particularly details on safety, please visit IXCHIQhcp.com/PI or contact your healthcare provider.

