



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Emergency Task Force

## PRAC-ETF considerations on the use of Ixchiq live attenuated virus vaccine against chikungunya

EMA's safety committee, PRAC, and EMA's Emergency Task Force (ETF) are aware of serious adverse events (SAEs) reported with Ixchiq, a live attenuated virus vaccine used to protect people in endemic areas and travellers to endemic areas against disease caused by the chikungunya virus. Chikungunya is a viral disease that mosquitoes can pass to humans.

The PRAC is reviewing available data. Until the PRAC communicates further, caution should be exercised when considering vaccination with Ixchiq in frail older adults, especially those with comorbidities potentially affecting immune responses to the vaccine.

Since January 2025, a large chikungunya outbreak has been affecting French overseas territories, prompting a vaccination campaign with the EU-authorized vaccine Ixchiq targeting individuals over 65 who have comorbidities and are at risk of severe disease. The campaign was later expanded to include all individuals aged 18 and older.

### Serious adverse events reported with Ixchiq

Globally as of 30 April 2025, 15 cases of SAEs following vaccination with Ixchiq have been reported by the marketing authorisation holder (MAH), including 9 from the European Union (8 from France including La Reunion) and 6 from the United States.

Of the 9 SAEs reported from the EU, 4 have occurred in people older than 80 years with multiple underlying comorbidities and who required hospitalisation. Two of these cases involved severe neurological complications in 84 years old individuals, which in one case led to death whilst the other patient is recovering in hospital. In both individuals, the vaccine strain of the chikungunya virus was detected in bodily fluids by polymerase chain reaction (PCR). Two other patients (84 and 82 years old) are recovering and have been discharged after 10 days of hospitalisation. More AEs have been reported since. On 25 April 2025, the French public health authority recommended a temporary suspension of vaccinations for individuals over 65 until the necessary investigations are completed.<sup>1</sup>

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<sup>1</sup> [Health authorities remove people aged 65 and over from the targets of the vaccination campaign against chikungunya with the IXCHIQ vaccine in Reunion Island and Mayotte - Ministry of Labour, Health, Solidarity and Families](#)

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The 6 SAEs reported from the United States occurred in travellers from 67 to 86 years of age and comprised of neurological or cardiac events. Five individuals were hospitalised and all have recovered. All 6 people had a number of existing comorbidities, such as prostate cancer, type 2 diabetes and chronic renal insufficiency. At their meeting on 16 April 2025, the Advisory Committee on Immunization Practices (ACIP) of the US Centers for Disease Control and Prevention (CDC) recommended precaution when vaccinating people older than 65 years depending on the risk of exposure.<sup>2</sup>

## **PRAC-ETF position**

The PRAC is reviewing the issue and will consider regulatory actions during its plenary meeting to begin on 5 May 2025.

Until the PRAC communicates further, caution should be used when considering vaccination with Ixchiq in frail older adults, especially those with comorbidities potentially affecting immune responses to the vaccine. As already stated in the summary of product characteristics (SmPC), Ixchiq must not be given to people who are immunodeficient or immunosuppressed due to a disease or treatment. As infection with chikungunya virus can have a significant impact on the health of elderly individuals, alternative vaccination strategies should be considered as available.

EMA supports efforts to use available vaccines to tackle the ongoing outbreak in La Reunion and surrounding areas and is contributing to efforts to conduct additional clinical research on the use of the vaccines in the regions affected.

## **More about chikungunya vaccines**

Two vaccines have been authorised in the EU since 2024 to prevent disease caused by the chikungunya virus: [Ixchiq](#) (Valneva) and [Vimkunya](#) (Bavarian Nordic). To date Ixchiq is the only vaccine against chikungunya that has been made available for use, and it is indicated for active immunisation of individuals over 12 years of age.

Ixchiq contains a live strain of chikungunya virus (strain CHIKV LR2006-OPY1) that has been attenuated (weakened). Clinical trials with Ixchiq showed that the vaccine induces high levels of neutralising antibodies in vaccinated individuals which are expected to provide protection based on non-clinical as well as epidemiological evidence. Ixchiq has also been authorised in the United States and Canada and is currently used in travellers.

The safety profile of Ixchiq was evaluated in around 4,000 individuals from clinical trials, including 350 older than 65 years. Chikungunya-like adverse reactions were reported in 12.1% of adult participants. The symptoms were mostly mild, but 1.8% of adult participants reported at least one severe symptom, most commonly fever or arthralgia. Longer-lasting symptoms ( $\geq 30$  days) occurred in 0.4% of participants. Based on these data, a warning in section 4.4 of the SmPC notes that Ixchiq may cause severe or prolonged chikungunya-like adverse reactions. Like other live attenuated vaccines, Ixchiq must not be given to people who are immunodeficient or immunosuppressed (people with a significantly weakened immune system) due to a disease or treatment.

According to the MAH, over 19,000 doses of Ixchiq are estimated to have been administered in the United States and over 12,000 doses in France and overseas French territories, of which around 6,400 doses were administered in La Reunion as of 25 April 2025. A little less than 6,000 doses have been used in Canada. More than half of the global vaccinations are estimated to have been given to

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<sup>2</sup> [ACIP CHIKUNGUNYA VACCINES WORK GROUP](#) ; [ACIP Meeting Information | ACIP | CDC](#)

individuals under 65 years However, these numbers represent estimates and are to be taken with caution as exact figures are not yet available

Vimkunya contains proteins from a chikungunya virus strain called Senegal strain 37997 (capsid protein and envelope proteins E1 and E2). These proteins are assembled into virus-like particles that are not infectious. Vimkunya was authorised in January 2025 and will be launched in the EU soon.

Regardless of vaccination, it is important to apply personal protection measures against mosquito bites. These include use of mosquito repellents and nets and wearing clothing that covers most of the body.

## Information on chikungunya

Chikungunya is a viral disease caused by chikungunya virus, a virus transmitted to humans by infected mosquitoes (primarily *Aedes aegypti* and *Aedes albopictus*).

The majority of people infected with chikungunya virus develop symptoms of acute disease within 3 to 7 days, most commonly fever and joint pain that last for about a week. However, some people develop joint pain for several months or longer, which can be disabling, and a small proportion of patients may develop severe acute disease, which can lead to multi-organ failure and death. Individuals deemed to have an increased risk of more severe disease include neonates, adults older than 65 years and people of any age with underlying comorbidities such as diabetes, heart disease, hypertension.

Chikungunya is mostly present in the tropics and subtropics. The majority of cases in the EU concern travellers who were infected outside of mainland Europe. However, following introduction by travellers, five outbreaks of autochthonous chikungunya virus infections have been reported since 2007, mainly in Italy and France where the *Aedes albopictus* mosquito is established.<sup>3</sup>

In 2025 no autochthonous cases of chikungunya disease have been reported in mainland Europe, but over 44,000 confirmed cases of chikungunya disease have been reported from the French overseas territory of [Reunion](#) as of 27 April 2025, including at least 9 fatal cases<sup>4</sup>.

More than 73,000 cases have been reported in South America since the beginning of the year until March 2025, the vast majority in Brazil, including 44 fatal cases. Fewer cases have been seen in Pakistan and Senegal<sup>5</sup>.

The spread of mosquitoes due to the consequences of climate change such as rising temperatures and changes in rainfall patterns could lead to cases of chikungunya in regions so far spared<sup>6</sup>.

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<sup>3</sup> [Local transmission of chikungunya virus in mainland EU/EEA, 2007–present](#)

<sup>4</sup> <https://www.santepubliquefrance.fr/recherche/#search=chikungunya>

<sup>5</sup> [Chikungunya worldwide overview](#)

<sup>6</sup> [Mosquito-borne diseases: an increasing risk in Europe](#)