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Ixchiq: temporary restriction on vaccinating people 65 years and older to be lifted

Vaccine to be used only when there is a significant chikungunya risk and after careful consideration of the benefits and risks

EMA's safety committee (PRAC) has completed its review of Ixchiq (a live attenuated chikungunya vaccine), following reports of serious side effects.

The previous temporary restriction on vaccinating people aged 65 years and above, which was put in place during the review, will now be lifted.

However, the Committee concluded that, for people of all ages, the vaccine should only be given when there is a significant risk of chikungunya infection and after a careful consideration of the benefits and risks.

What the safety data show

Serious side effects with the vaccine were reported mainly in people 65 years of age and older and in those with several underlying medical conditions. These side effects led to a worsening of the patients' medical conditions or a deterioration in their general health, in some cases leading to hospitalisation and death.

Many of the serious side effects reported are similar to symptoms of chikungunya infection and include fever, malaise (feeling unwell), loss of appetite and confusion, which can lead to falls. Chikungunya-like symptoms are mostly mild, but some adults (about 2 people in 100) may develop more severe symptoms.

The Committee also reviewed cases of encephalitis (inflammation of the brain) with symptoms such as confusion, sleepiness, fever and headache. Cases of encephalitis are rare and the frequency with which they occur is not known.

The benefits and risks in older people

While most serious side effects occurred in older people, Ixchiq is effective at triggering the production of antibodies against the chikungunya virus which may be of particular benefit for older people who are at increased risk of severe chikungunya infection.

The Committee therefore concluded that the vaccine should only be given when there is a significant risk of chikungunya infection and after a careful consideration of the benefits and risks.

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People with weakened immune systems

Healthcare professionals are reminded that Ixchiq must not be given to people whose immune system is weakened because of disease or medical treatment. People with a weakened immune system are at greater risk of having complications from vaccines containing live attenuated viruses such as Ixchiq.

The vaccine was already contraindicated in people with weakened immune systems, and the contraindication remains in place. The product information for Ixchiq will be updated with the latest recommendations following this review.

Ixchiq was authorised in the EU in June 2024. At the start of the review, around 36,000 doses of the vaccine had been used worldwide.

Information for the public

- Some people have experienced serious side effects after vaccination with Ixchiq. People affected were mainly 65 years of age and older or people with chronic medical conditions.
- Most serious side effects resemble symptoms of chikungunya infection and include fever, malaise (feeling unwell), loss of appetite and confusion, which may lead to falls.
- There have also been rare cases of encephalitis (inflammation in the brain) causing symptoms such as confusion, sleepiness, fever and headache. If you experience these symptoms, seek medical attention immediately.
- Tell your healthcare professional if your general health or another medical condition worsens soon after vaccination.
- Ixchiq is effective at triggering the production of antibodies against the chikungunya virus which may be of particular benefit for older people who are at increased risk of severe chikungunya disease.
- Before you receive Ixchiq, your healthcare professional will consider your risk of acquiring chikungunya infection and carefully weigh the benefits and risks for you if you take the vaccine.
- If you have any questions about taking the vaccine, speak to your healthcare professional.

Information for healthcare professionals

- The temporary contraindication for people aged 65 years and above, which was in place during the review, has now been lifted.
- The PRAC recommended that the vaccine should only be given when there is a significant risk of acquiring chikungunya infection and after a careful consideration of the benefits and risks.
- A review of safety data has revealed 28 cases of serious side effects with Ixchiq which occurred mainly in people aged 65 years and older and in those with multiple chronic or uncontrolled medical conditions, such as cardiovascular diseases, diabetes mellitus or chronic kidney disease.
- Among the side effects are encephalitis and chikungunya-like symptoms, which may lead to the worsening of the patients' medical conditions or a deterioration in their general health. Three of the cases reported resulted in death.

- The PRAC noted that older people may derive the most benefit from vaccination as this group is at higher risk of serious or complicated chikungunya disease.

A direct healthcare professional communication (DHPC) will be sent to healthcare professionals prescribing or administering the medicine. The DHPC will also be published on a dedicated page on the EMA website.

More about the medicine

Ixchiq is a vaccine used to help protect people 12 years of age and older against chikungunya disease. It contains a strain of the chikungunya virus that has been attenuated (weakened).

When a person is given Ixchiq, the immune system recognises the weakened virus as 'foreign' and makes antibodies against it. If the person later comes into contact with the chikungunya virus, the immune system will be able to fight off the virus more effectively and so help to protect the person against chikungunya.

Most people infected with the chikungunya virus develop symptoms within 3–7 days. The most common symptoms of acute disease are fever and joint pain. Other symptoms can include headache, muscle pain, joint swelling, or rash. Most patients recover within a week, but some develop joint pain for several months or longer, which can be disabling. A small proportion of patients may develop severe acute disease, which can lead to multiorgan failure and is most often observed in newborns exposed to the virus during childbirth and adults over 65 years old.

More about the procedure

The review of Ixchiq was initiated on 5 May 2025 at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations.

The PRAC recommendations will now be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.