EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 9 – 12 March 2026

PRAC warns about known risk of aseptic meningitis with chikungunya vaccine Ixchiq

Update to product information recommended to reflect recent evidence

EMA's safety committee (PRAC) has completed its review of a safety signal of aseptic meningitis with Ixchiq (live attenuated chikungunya vaccine) and has recommended an update to the vaccine's product information to reflect the most recent evidence related to this known risk.

The safety signal was started following a reported case of aseptic meningitis which occurred in a healthy young adult following vaccination with Ixchiq. Aseptic meningitis is an inflammation of the membranes that surround the brain and spinal cord, typically caused by viruses rather than bacteria.

Aseptic meningitis as well as encephalopathy and encephalitis (other disorders of the nervous system) are already listed in the product information of Ixchiq as known side effects with an unknown frequency (meaning that the available data do not allow estimating how often the side effects occur). Symptoms include confusion, sleepiness, fever, headache, seizures and neck stiffness. Anyone who develops these symptoms after receiving Ixchiq should seek medical attention immediately.

Ixchiq's product information will now be updated to reflect that serious side effects, such as aseptic meningitis, have also been observed in healthy young adults. Previously, most reported cases had occurred in older people (over 65 years of age) or people with multiple long-term medical conditions.

PRAC is also carrying out an evaluation of Ixchiq in the context of a regular 6-monthly PSUR (periodic safety update report) assessment, which will conclude in June 2026. This will allow assessing whether newly available information relating to the risk of aseptic meningitis, or any other emerging safety information, has an impact on the balance of benefits and risks of Ixchiq.

As for any medicine, the safety of Ixchiq is closely monitored and the recommendations for use will be updated if new, relevant information becomes available.

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PRAC statistics: March 2026

[infographic]

Glossary:

Safety signal assessments. A safety signal is information which suggests a new potentially causal association, or a new aspect of a known association between a medicine and an adverse event that warrants further investigation. Safety signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. More information can be found under 'Signal management'.

Periodic safety update reports, abbreviated as PSURs, are reports prepared by the marketing authorisation holder to describe the worldwide safety experience with a medicine in a defined period after its authorisation. PSURs for medicinal products that contain the same active substance or the same combination of active substances but have different marketing authorisations and are authorised in different EU Member States, are jointly assessed in a single assessment procedure. More information can be found under 'Periodic safety update reports: questions and answers'.

Risk management plans, abbreviated as RMPs, are detailed descriptions of the activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicines. Companies are required to submit an RMP to EMA when applying for a marketing authorisation. RMPs are continually updated throughout the lifetime of the medicine as new information becomes available. More information is available under 'Risk-management plans'.

Post-authorisation safety studies, abbreviated as PASSs, are studies carried out after a medicine has been authorised to obtain further information on its safety, or to measure the effectiveness of risk-management measures. The PRAC assesses the protocols (aspects related to the organisation of a study) and the results of PASSs. More information can be found under 'Post-authorisation safety studies'.

Referrals are procedures used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral related to safety of medicines, the PRAC is requested by a Member State or the European Commission to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. More information can be found under referral procedures.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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