



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

## New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 9-12 March 2026 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found on the webpage for [PRAC recommendations on safety signals](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

### 1. Chikungunya vaccine (live) – New aspect of the known risk of aseptic meningitis (EPITT no 20250)

#### Summary of product characteristics

##### 4.4 Special warnings and precautions for use

Serious adverse reactions have been reported with the use of IXCHIQ, particularly in individuals aged 65 years and older and in individuals with multiple underlying chronic and/or uncontrolled medical conditions, but also in young adults with no relevant comorbidities (see section 4.8). Severe reactogenicity or chikungunya-like adverse reactions may lead to deterioration of general condition including malaise and decreased appetite, exacerbation of pre-existing diseases, confusional state, aseptic meningitis, encephalopathy, or encephalitis, leading to falls, hospitalisation and death. [...]

##### 4.8 Undesirable effects

Adults ≥ 18 years of age

In the post-marketing setting, serious adverse reactions have been reported, particularly in males aged 65 years and older with underlying chronic medical conditions such as cardiovascular disease, diabetes mellitus or chronic kidney disease, but also in young adults with no relevant comorbidities.

<sup>1</sup> Expected publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



These adverse reactions included neurological events such as fatal encephalitis, aseptic meningitis, deterioration of general condition, and exacerbation of chronic medical conditions (see section 4.4).

### **Package leaflet**

2 What you need to know before you receive IXCHIQ

### **Warnings and precautions**

[...] Serious reactions to the vaccine have been reported mostly in persons 65 years and older and in persons with chronic medical conditions, such as high blood pressure, diabetes or heart disease, but also in healthy young adults. [...]

## **2. Galantamine – Nightmares (EPITT no 20196)**

### **Summary of product characteristics**

4.8 Undesirable effects

Psychiatric disorders

Frequency "Uncommon":

Nightmare

### **Package leaflet**

4 Possible side effects

Frequency "Uncommon":

Nightmares