



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 29-31 October 2018 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 [here](#) (in English only).

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

1. Tacrolimus systemic formulation – Hepatitis E infection (EPITT no 19246)

Summary of product characteristics

4.4. Special warnings and precautions for use

Infections including opportunistic infections

Patients treated with immunosuppressants, including tacrolimus are at increased risk for infections including opportunistic infections (bacterial, fungal, viral and protozoal). ~~Among these conditions are such as~~ BK virus associated nephropathy and JC virus associated progressive multifocal leukoencephalopathy (PML). Patients are also at an increased risk of infections with viral hepatitis (for example, hepatitis B and C reactivation and de novo infection, as well as hepatitis E, which may become chronic). These infections are often related to a high total immunosuppressive burden and may lead to serious or fatal conditions that physicians should consider in the differential diagnosis in immunosuppressed patients with deteriorating hepatic or renal function or neurological symptoms. Prevention and management should be in accordance with appropriate clinical guidance.

¹ Intended publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



2. Xylometazoline – Serious ventricular arrhythmia in patients with long QT syndrome (EPITT no 19242)

Summary of product characteristics

4.4. Special warnings and precautions for use

Patients with long QT syndrome treated with xylometazoline may be at increased risk of serious ventricular arrhythmias.

Package leaflet

2. What you need to know before you use <Product name>

Warnings and precautions

Talk to your doctor or pharmacist before using <Product name>

- if you suffer from a heart disease (e.g. long QT syndrome)

Note: in the package leaflet the text '(e.g. long QT syndrome)' should be added to the bullet point mentioning heart disease, taking into account the already existing wording for nationally authorised medicinal products. For package leaflets which do not mention 'heart disease', a bullet point on 'heart disease (e.g. long QT syndrome)' should be added, in line with the wording above.