



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/PRAC/143100/2025  
Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 5-8 May 2025 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. Sertraline – Multiple acyl-coenzyme A dehydrogenase deficiency (MADD) (EPITT no 20125)

*Taking into account the already existing wording in some nationally authorised products, the text may need to be adapted by marketing authorisation holders to individual products.*

#### Summary of product characteristics

##### 4.8 Undesirable effects

Table 1: Adverse reactions

Musculoskeletal and connective tissue disorders

Frequency "Not known":

Multiple acyl-coenzyme A dehydrogenase deficiency (MADD)-like disorder\*

\* ADR identified post-marketing

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



## Package leaflet

### 4. Possible side effects

Frequency "Not known":

Muscle weakness and severe muscle pain, which can be a sign of multiple acyl-coenzyme A dehydrogenase deficiency (MADD)-like disorder.

## 2. Sulfamethoxazole, trimethoprim (cotrimoxazole) – Circulatory shock (EPITT no 20135)

*Taking into account the already existing wording in some nationally authorised products, the text may need to be adapted by marketing authorisation holders to individual products.*

### Summary of product characteristics

#### 4.8 Undesirable effects

Vascular disorders

Frequency "Not known":

Circulatory shock

Description of selected adverse reactions

...

Circulatory shock

Cases of circulatory shock, often accompanied by fever and not responding to standard treatment for hypersensitivity, have been reported with sulfamethoxazole + trimethoprim, mainly in immunocompromised patients.

## Package leaflet

### 4. Possible side effects

Serious side effects

Call the emergency department immediately if you experience multiple symptoms such as fever, very low blood pressure or increased heart rate after taking this drug as it may be a sign of shock.