



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 September 2026¹
EMA/PRAC/183503/2026
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 31 August-3 September 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. Oxacillin – Drug reaction with eosinophilia and systemic symptoms (DRESS) (EPITT no 20223)

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

4.4 Special warnings and precautions for use

The following warning should be added under the paragraph concerning hypersensitivity reactions.

Severe cutaneous adverse reactions (SCARs)

Drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, has been reported in association with oxacillin treatment (see section 4.8). Patients should be advised of the signs and symptoms of this severe cutaneous adverse reaction and should seek medical advice from their physician immediately when observing any indicative signs or symptoms. If signs and symptoms suggestive of DRESS appear, {Invented name} should be withdrawn immediately and an alternative treatment considered (as appropriate). If the patient has developed a severe cutaneous

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



adverse reaction such as DRESS, treatment with oxacillin must not be restarted in this patient at any time.

4.8 Undesirable effects

Skin and subcutaneous tissue disorders

Frequency “Not known”:

Drug reaction with eosinophilia and systemic symptoms (DRESS)

Package leaflet

For products with intravenous/intramuscular route of administration:

2 What you need to know before you use {Invented name}

Warnings and precautions

Talk to your doctor before using {Invented name} if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using this medicine or other related active substances such as other penicillins. This medicine can cause serious skin reaction. Seek medical attention immediately if you notice any of the symptoms related to this serious skin reaction described in section 4.

4 Possible side effects

Seek medical attention immediately if you notice any of the following symptoms of serious skin reactions:

Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

For products with oral administration:

2 What you need to know before you take {Invented name}

Warnings and precautions

Talk to your doctor before taking {Invented name} if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using this medicine or other related active substances such as other penicillins. This medicine can cause serious skin reactions. Stop taking {Invented name} and seek medical attention immediately if you notice any of the symptoms related to this serious skin reaction described in section 4.

4 Possible side effects

Stop taking {Invented name} and seek medical attention immediately if you notice any of the following symptoms of serious skin reactions:

Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).