

3 April 2018¹
EMA/PRAC/136578/2018
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 5-8 March 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. Cefalexin – Acute generalised exanthematous pustulosis (AGEP) (EPITT no 18911)

Summary of product characteristics

4.4. Special warnings and precautions for use

Acute generalised exanthematous pustulosis (AGEP) has been reported in association with cefalexin treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, cefalexin should be withdrawn immediately and an alternative treatment considered. Most of these reactions occurred most likely in the first week during treatment.

4.8. Undesirable effects

Table of ADRs:

Skin and subcutaneous tissue disorders (frequency: not known)

Acute generalised exanthematous pustulosis (AGEP)

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

Package leaflet

2. What do you need to know before you use cefalexin

TELL YOUR DOCTOR BEFORE TAKING CEFALEXIN:

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefalexin or other antibacterials

Warnings and precautions – Take special care with cefalexin:

Acute generalised exanthematous pustulosis (AGEP) has been reported with the use of cefalexin. AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities. The highest risk for occurrence of this serious skin reaction is within the first week of treatment. If you develop a serious rash or another of these skin symptoms, stop taking cefalexin and contact your doctor or seek medical attention immediately.

4. Possible side effects

Frequency not known:

A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using cefalexin if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

2. Norepinephrine – Stress cardiomyopathy (EPITT no 19172)

Summary of product characteristics

4.8. Undesirable effects

Cardiac disorders

Frequency 'not known': Stress cardiomyopathy