9 February 2026[1]
EMA/PRAC/1401/2026
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 12-15 January 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. Cefazolin; cefazolin, lidocaine hydrochloride – Kounis syndrome (EPITT no 20204)

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

Hypersensitivity

Cases of Kounis syndrome have been reported in patients treated with cefazolin. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

4.8 Undesirable effects

Cardiac disorders with frequency "Not known"

Kounis syndrome

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Package leaflet

2 - What you need to know before you take <product name>

Warnings and precautions

Signs of an allergic reaction to this medicine, including breathing problems and chest pain, have been reported with cefazolin. Stop immediately cefazolin and contact immediately your doctor or medical emergencies if you notice any of these signs.

4 - Possible side effects

Other possible side effects

Not known (frequency cannot be estimated from the available data)

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

2. Erdafitinib – Growth accelerated (EPITT no 20194)

Summary of product characteristics

4.2 Posology and method of administration

Paediatric population

There is no relevant use of erdafitinib in the paediatric population for the treatment of urothelial carcinoma. The safety and efficacy of erdafitinib in paediatric patients (<18 years of age) have not been established. Currently available safety data are described in section 4.8.

4.8 Undesirable effects

(under 'Description of selected adverse reactions' and after the paragraph on 'Abnormal laboratory findings')

Paediatric population

Growth acceleration and epiphysiolysis of the femoral head have been reported in paediatric patients (<18 years of age) receiving erdafitinib in clinical trials outside of the authorised indication and off label in the post-marketing setting.

5.1 Pharmacodynamic properties

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with erdafitinib in all subsets of the paediatric population in urothelial carcinoma (see ~~section~~ sections 4.2 and 4.8 for information on paediatric use).

Package leaflet

2 What you need to know before you take Balversa

Children and adolescents

This medicine is not for use in children and adolescents. This is because there is ~~no~~ limited experience with using Balversa in this age group. See section 4 for more information.

4 Possible side effects

Additional side effects in children and adolescents

Balversa may cause accelerated growth or irregular hip joint growth or damage in paediatric patients (<18 years of age). If you or your child experience pain in the hip or knee or have an unexplained limp, talk to your doctor.

3. Pegylated liposomal doxorubicin – Renal-limited thrombotic microangiopathy (EPITT no 20193)

Summary of product characteristics

4.8 Undesirable effects

Renal and urinary disorders

Renal-limited thrombotic microangiopathy: frequency – not known

Package leaflet

4 Possible side effects

Not known (frequency cannot be estimated from the available data)

- clogging of very small blood vessels in the kidneys (renal-limited thrombotic microangiopathy)