



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 4-7 March 2024 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. Abemaciclib; palbociclib; ribociclib – Erythema multiforme (EPITT no 19973)

Summary of product characteristics

Abemaciclib

4.8 Undesirable effects

Table 8. Adverse reactions reported in the phase 3 studies of abemaciclib in combination with endocrine therapy (N = 3 559) and during post-marketing experience

Skin and subcutaneous tissue disorders

Frequency 'rare': Erythema multiforme

Ribociclib

4.8 Undesirable effects

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



Table 7. Adverse reactions reported in the three phase III clinical studies and during post-marketing experience

Skin and subcutaneous tissue disorders

Frequency 'rare': Erythema multiforme

~~* Adverse reaction reported during post-marketing experience. [All asterisks applied on adverse events of the table should be removed accordingly]~~

Palbociclib

4.8 Undesirable effects

Table 4. Adverse reactions based on pooled dataset from 3 randomised studies (N=872) and during post-marketing experience

Skin and subcutaneous tissue disorders	All Grades n (%)	Grade 3 n (%)	Grade 4 n (%)
<i>Uncommon</i> <u>Erythema multiforme</u>	<u>1 (0.1)</u>	<u>0 (0.0)</u>	<u>0 (0.0)</u>

~~* Adverse drug reaction identified post-marketing. [All asterisks applied on adverse events of the table should be removed accordingly]~~

Package leaflet

4. Possible side effects

Under frequency 'rare' for Abemaciclib and for Ribociclib

Under frequency 'uncommon' for Palbociclib

A skin reaction that causes red spots or patches on the skin that may look like a target or "bullseye" with a dark red centre surrounded by paler red rings (erythema multiforme).