EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/PRAC/206903/2026
Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 28 September-1 October 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. Binimetinib; encorafenib – Neutropenia, febrile neutropenia (EPITT no 20255)

**ENCORAFENIB**

**Summary of product characteristics**

4.8 – Undesirable effects

Table 5 - "Encorafenib 450 mg in combination with binimetinib" column

Blood and lymphatic system disorders

Frequency "Common":

Neutropenia

**Package leaflet**

4. Possible side effects

Side effects when Braftovi and binimetinib are taken together for treatment of melanoma or NSCLC

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

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Common (may affect up to 1 in 10 people)

- some types of skin tumours such as skin papilloma

- decrease in the number of white blood cells, cells that fight infection (neutrophils)

**BINIMETINIB**

**Summary of product characteristics**

4.8 – Undesirable effects

Blood and lymphatic system disorders

Frequency "Common":

Neutropenia

**Package leaflet**

4. Possible side effects

Other side effects when Mektovi and encorafenib are taken together

Common (may affect up to 1 in 10 people)

- some types of skin tumours such as skin papilloma

- decrease in the number of white blood cells, cells that fight infection (neutrophils)