



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/PRAC/207873/2023  
Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 10-12 May 2023 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. Lenvatinib – Adrenal insufficiency (EPITT no 19870)

#### Summary of product characteristics for Lenvima

##### 4.8. Undesirable effects

Endocrine disorders

Lenvatinib monotherapy: frequency "uncommon": adrenal insufficiency

Combination with pembrolizumab: frequency "common": adrenal insufficiency

#### Summary of product characteristics for Kisplyx

##### 4.8. Undesirable effects

Endocrine disorders

Monotherapy/combination with everolimus: frequency "uncommon": adrenal insufficiency

Combination with pembrolizumab: frequency "common": adrenal insufficiency

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



### **Package leaflet for Lenvima**

#### 4. Possible side effects

The following side effects may happen with this medicine when given alone:

Uncommon (may affect up to 1 in 100 people)

- decreased secretion of hormones produced by the adrenal glands

The following side effects may happen with this medicine when given in combination with pembrolizumab:

Common (may affect up to 1 in 10 people)

- decreased secretion of hormones produced by the adrenal glands

### **Package leaflet for Kisplyx**

#### 4 - Possible side effects

Common (may affect up to 1 in 10 people)

- decreased secretion of hormones produced by the adrenal glands