10 February 2025[1]
EMA/PRAC/6379/2025
Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 13-16 January 2025 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. Afatinib – Growth of eyelashes (EPITT no 19987)

**Summary of product characteristics**

4.8 Undesirable effects

Eye disorders

Frequency "uncommon":

Aberrant eyelash growth

**Package leaflet**

4. Possible side effects

Uncommon side effects (may affect up to 1 in 100 people):

- Abnormal growth of your eyelash (including misdirected growth that may lead to damage to the eye surface)

[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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# 2. Lenvatinib – Tumour lysis syndrome (EPITT no 20108)

**Summary of product characteristics**

4.4 Special warnings and precautions for use

For Lenvima and Kisplyx:

Tumour lysis syndrome (TLS)

Lenvatinib can cause TLS which can be fatal. Risk factors for TLS include but are not limited to high tumour burden, pre-existing renal impairment and dehydration. These patients should be monitored closely and treated as clinically indicated, and prophylactic hydration should be considered.

4.8 Undesirable effects

For Lenvima:

| **Table 6 Adverse reactions reported in patients treated with lenvatinib§** | | |
|---|---|---|
| **System Organ Class** (MedDRA terminology) | **Lenvatinib monotherapy** | **Combination with pembrolizumab** |
| **Metabolism and nutrition disorders** | | |
| Rare | Tumour lysis syndrome† | Tumour lysis syndrome† |

†: Includes cases with a fatal outcome.

For Kisplyx:

| **Table 4 Adverse reactions reported in patients treated with lenvatinib§** | | | |
|---|---|---|---|
| **System Organ Class** (MedDRA terminology) | **Lenvatinib monotherapy** | **Combination with everolimus** | **Combination with pembrolizumab** |
| **Metabolism and nutrition disorders** | | | |
| Rare | Tumour lysis syndrome† | Tumour lysis syndrome† | Tumour lysis syndrome† |

†: Includes cases with a fatal outcome.

**Package leaflet**

For Lenvima and Kisplyx:

2. What you need to know before you take <x>

Conditions you need to look out for

During treatment of your cancer, the breakdown of tumour cells may leak substances into the blood which may lead to a group of complications called tumour lysis syndrome (TLS). This may lead to changes in your kidneys and can be life-threatening. Your doctor will observe and may give you a treatment to reduce the risk. Tell your doctor immediately if you experience signs of TLS (see section 4: Possible side effects).

4. Possible side effects

Tell your doctor straight away if you notice any of the following side effects - you may need urgent medical treatment:

- nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness. These symptoms may be complications due to the breakdown products of dying cancer cells and known as tumour lysis syndrome (TLS).

TLS should be added to the sections, where relevant, of "when given alone", "when given in combination with everolimus" and "when given in combination with pembrolizumab".

Rare (may affect up to 1 in 1,000 people)

- Tumour lysis syndrome (TLS)