



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 June 2024¹
EMA/PRAC/222450/2024
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 13-16 May 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. Baricitinib – Hypoglycaemia in diabetic patients (EPITT no 20038)

Summary of product characteristics

4.4 Special warnings and precautions for use

Hypoglycaemia in patients treated for diabetes

There have been reports of hypoglycaemia following initiation of JAK inhibitors, including baricitinib, in patients receiving medication for diabetes. Dose adjustment of anti-diabetic medication may be necessary in the event that hypoglycaemia occurs.

Package leaflet

2. What you need to know before you take OLUMIANT

Other medicines and OLUMIANT

Tell your doctor or pharmacist if you are taking, have recently taken, or might take, any other medicines.

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



In particular, tell your doctor or pharmacist before taking Olumiant if you are taking any other medicine such as:

[...]

- medicines to treat diabetes or if you have diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking Olumiant.

2. Dabrafenib; trametinib – Acute febrile neutrophilic dermatosis (EPITT no 20022)

Summary of product characteristics

Tafinlar

4.8 Undesirable effects

Table 3 - Adverse reactions with dabrafenib monotherapy and Table 4 - Adverse reactions with dabrafenib in combination with trametinib

Skin and subcutaneous tissue disorders

Frequency Uncommon: Acute febrile neutrophilic dermatosis

Mekinist

4.8 Undesirable effects

Table 5 Adverse reactions with trametinib in combination with dabrafenib

Skin and subcutaneous tissue disorders

Frequency Uncommon: Acute febrile neutrophilic dermatosis

Finlee

4.8 Undesirable effects

Adverse reactions ~~in the integrated paediatric safety population~~ (Table 4) are listed below by MedDRA system organ class [...]

Table 4 Adverse reactions ~~reported in the integrated paediatric safety population of~~ with dabrafenib in combination with trametinib (~~n=171~~)

Skin and subcutaneous tissue disorders	
Uncommon	<u>Acute febrile neutrophilic dermatosis¹⁰ [...]</u>
¹⁰	<u>Acute febrile neutrophilic dermatosis is an adverse drug reaction seen also with dabrafenib monotherapy (Tafinlar)</u>
[...]	

Spexotras

4.8 Undesirable effects

Adverse reactions ~~in the integrated paediatric safety population~~ (Table 5) are listed below by MedDRA system organ class [...]

Table 5 Adverse reactions ~~reported in the integrated paediatric safety population of~~ with trametinib in combination with dabrafenib (~~n=171~~)

Skin and subcutaneous tissue disorders	
Uncommon	<u>Acute febrile neutrophilic dermatosis [...]</u>

Package leaflet

Tafinlar

4. Possible side effects

Possible side effects in patients taking Tafinlar alone

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

- Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms, legs, face and neck, with a fever (signs of acute febrile neutrophilic dermatosis)

Possible side effects when Tafinlar and trametinib are taken together

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

- Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms, legs, face and neck, with a fever (signs of acute febrile neutrophilic dermatosis)

Mekinist

4. Possible side effects

Side effects when Mekinist and dabrafenib are taken together

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

- Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms, legs, face and neck, with a fever (signs of acute febrile neutrophilic dermatosis)

Finlee and Spexotras

4. Possible side effects

Other possible side effects

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

- Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms, legs, face and neck, with a fever (signs of acute febrile neutrophilic dermatosis)

3. Manidipine – Ascites (EPITT no 20026)

Summary of product characteristics

4.4 Special warnings and precautions for use

Peritoneal dialysis

Manidipine has been associated with the development of cloudy peritoneal effluent in patients on peritoneal dialysis. The turbidity is due to an increased triglycerides concentration in the peritoneal effluent and tends to resolve after discontinuation of manidipine. This is an important association to recognise as cloudy peritoneal effluent can be mistaken for infective peritonitis with consequential unnecessary hospitalisation and empiric antibiotic administration.

4.8 Undesirable effects

Gastrointestinal disorders

Frequency “Not known”: Peritoneal cloudy effluent

Package leaflet

2. What you need to know before you take <Product name>

Warnings and precautions

Talk to your doctor before taking <Product name>

- [...]
- If you are undergoing peritoneal dialysis

4. Possible side effects

Frequency not known (frequency cannot be estimated from the available data): [...], cloudy fluid (when performing dialysis through a tube into your abdomen)

4. Propofol – Hepatic failure (EPITT no 20020)

Summary of product characteristics

4.8 Undesirable effects

Frequency: not known

Hepatitis, acute hepatic failure.

Footnote to section 4.8: After both long- and short-term treatment and in patients without underlying risk factors.

Package leaflet*

4. Possible side effects

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

Hepatitis (inflammation of the liver), acute liver failure (symptoms can include yellowing skin and eyes, itching, dark coloured urine, stomach pain and liver tenderness (indicated by pain under the front of the rib cage on your right-hand side), sometimes with loss of appetite).

**If package leaflets distinguish between adverse reactions that could occur during anaesthesia and adverse reactions that could occur after anaesthesia, these ADRs are recommended to be included amongst ADRs that could occur after anaesthesia.*