



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 25-28 October 2021 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. Ertapenem – Toxic encephalopathy in patients with renal impairment (EPITT no 19498)

Summary of product characteristics

4.4. Special warnings and precautions for use

Encephalopathy

Encephalopathy has been reported with the use of ertapenem (see section 4.8). If ertapenem-induced encephalopathy is suspected (e.g. myoclonus, seizures, altered mental status, depressed level of consciousness), discontinuation of ertapenem should be considered. Patients with renal impairment are at higher risk of ertapenem-induced encephalopathy and the resolution may be prolonged.

4.8. Undesirable effects

Adults 18 years of age and older

Nervous system disorders

Frequency 'not known': encephalopathy (see section 4.4)

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



2. Labetalol – Nipple pain and suppressed lactation (EPITT no 19639)

Summary of product characteristics

4.6. Fertility, pregnancy and lactation

Breast-feeding

- Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4.8).

4.8. Undesirable effects

Reproductive system and breast disorders

Frequency 'not known': Nipple pain, Raynaud's phenomenon of the nipple

Package leaflet

2. What you need to know before you take [product name]

Pregnancy, breast-feeding and fertility

- Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4).

4. Possible side effects

Not known (cannot be estimated from the available data)

- Nipple pain
- Intermittent decrease in blood flow to your nipples, which may cause your nipples to go numb, pale, and painful (Raynaud's phenomenon)

3. Lenvatinib – Colitis (EPITT no 19691)

Summary of product characteristics

4.8. Undesirable effects

Gastrointestinal disorders

Frequency 'uncommon': Colitis

Package leaflet

4. Possible side effects

Other side effects include:

Uncommon (may affect up to 1 in 100 people)

Inflammation of the colon (colitis)