26 October 2020[1]
EMA/PRAC/513093/2020
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 28 September-1 October 2020 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. Citalopram; desvenlafaxine; escitalopram; fluoxetine; fluvoxamine; milnacipran; paroxetine; sertraline; venlafaxine; vortioxetine – Postpartum haemorrhage (EPITT no 19552)

For citalopram, desvenlafaxine, escitalopram, fluoxetine, fluvoxamine, milnacipran, paroxetine, sertraline, venlafaxine

Summary of product characteristics

4.4. Special warnings and precautions for use

SSRIs/SNRIs may increase the risk of postpartum haemorrhage (see sections 4.6, 4.8).

4.6. Fertility, pregnancy and lactation

Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth (see sections 4.4, 4.8).

[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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4.8. Undesirable effects

Reproductive system and breast disorders: postpartum haemorrhage*; frequency not known

* This event has been reported for the therapeutic class of SSRIs/SNRIs (see sections 4.4, 4.6).

Package leaflet

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

Warnings and precautions

Talk to your doctor before taking <product name>, especially if you have:

- History of bleeding disorders […], or if you are pregnant (see 'Pregnancy'[2])

Pregnancy[2]

If you take <product name> near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking <product name> so they can advise you.

4. Possible side effects

Frequency not known

• Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy[2] in section 2 for more information

For vortioxetine

Summary of product characteristics

4.4. Special warnings and precautions for use

Haemorrhage

[…] SSRIs/SNRIs may increase the risk of postpartum haemorrhage, and this risk could potentially apply also to vortioxetine (see section 4.6). […]

4.6. Fertility, pregnancy and lactation

Observational data have provided evidence of an increased risk (less than 2-fold) of postpartum haemorrhage following exposure to an SSRI or SNRI within the month prior to birth. Although no studies have investigated an association between vortioxetine treatment and postpartum haemorrhage, there is a potential risk, taking into account the related mechanism of action (see section 4.4).

Package leaflet

2. What you need to know before you take Brintellix

[2] In some medicinal products the relevant section may be called 'Pregnancy, breast-feeding and fertility'.

Warnings and precautions

Talk to your doctor or pharmacist before taking Brintellix if you:

- have a tendency to bleed or bruise easily, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility')

Pregnancy, breast-feeding and fertility

If you take Brintellix near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Brintellix so they can advise you.

2. Pembrolizumab – Sjogren's syndrome (EPITT no 19564)

Summary of product characteristics

4.8. Undesirable effects

Tabulated list of adverse reactions

Table 2: Adverse reactions in patients treated with pembrolizumab

	Monotherapy	Combination with chemotherapy	Combination with axitinib
Musculoskeletal and connective tissue disorders			
Uncommon	[…]	[…]	Sjogren's syndrome
Rare	Sjogren's syndrome	Sjogren's syndrome	

Package leaflet

4. Possible side effects

The following side effects have been reported with pembrolizumab alone:

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

- disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome)

The following side effects have been reported in clinical studies with pembrolizumab in combination with chemotherapy:

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

- disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome)

The following side effects have been reported in clinical studies with pembrolizumab in combination with axitinib:

Uncommon (may affect up to 1 in 100 people)

- disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome)