



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 12-15 March 2019 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. Nivolumab – Hypoparathyroidism (EPITT no 19310)

Summary of product characteristics

4.4. Special warnings and precautions for use

Other immune-related adverse reactions: [...] Cases of Vogt-Koyanagi-Harada syndrome and hypoparathyroidism have been reported post-marketing (see section 4.8).

4.8. Undesirable effects

Hypoparathyroidism^h

Frequency: Not known for nivolumab monotherapy / nivolumab in combination with ipilimumab
[Table key: ^h Post-marketing event (also see section 4.4)]

Package Leaflet

2. What you need to know before you use OPDIVO

Warnings and precautions

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



[...]

Problems with your hormone producing glands (including the pituitary, the thyroid, the parathyroid and adrenal glands) that may affect how these glands work. Signs and symptoms that these glands are not working properly may include fatigue (extreme tiredness), weight change or headache, decreased blood levels of calcium and visual disturbances.

4. Possible side effects

[...]

- Decreased function of the parathyroid gland

2. Paracetamol – Paracetamol use in pregnancy and child neurodevelopment and effects on the urogenital apparatus (EPITT no 17796)

Summary of product characteristics

4.6. Fertility, pregnancy and lactation

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

5.3. Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

Package leaflet

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

Pregnancy and breast-feeding

If necessary, <Product name> can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your <doctor><midwife> if the pain and/or fever are not reduced or if you need to take the medicine more often.