8 July 2019[1]
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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 11-14 June 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. Loperamide – Brugada syndrome in the context of abuse with loperamide (EPITT no 19379)

Summary of product characteristics

4.4. Special warnings and precautions for use

[…] Overdose can unmask existing Brugada syndrome. […]

4.9. Overdose

[…] Overdose can unmask existing Brugada syndrome.

2. Propylthiouracil – Risk of congenital anomalies (EPITT no 19358)

Summary of product characteristics

4.6. Fertility, pregnancy and lactation

Women of childbearing potential

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

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Women of childbearing potential should be informed about the potential risks of propylthiouracil use during pregnancy.

Pregnancy

Hyperthyroidism in pregnant women should be adequately treated to prevent serious maternal and foetal complications.

Propylthiouracil is able to cross the human placenta.

Animal studies are insufficient with respect to reproductive toxicity. Epidemiological studies provide conflicting results regarding the risk of congenital malformations.

Individual benefit/risk assessment is necessary before treatment with propylthiouracil during pregnancy. Propylthiouracil should be administered during pregnancy at the lowest effective dose without additional administration of thyroid hormones. If propylthiouracil is used during pregnancy, close maternal, foetal and neonatal monitoring is recommended.

Package leaflet

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

Pregnancy

The potential of [Product name] to cause harm to an unborn baby is uncertain.

If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor straight away. You may need treatment with [Product name] during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.

3. Rivaroxaban – Premature ending of the GALILEO study in patients who have received an artificial heart valve through a transcatheter aortic valve replacement (TAVR) (EPITT no 19294)

Summary of product characteristics

4.4. Special warnings and precautions for use

Patients with prosthetic valves

Rivaroxaban should not be used for thromboprophylaxis in patients having recently undergone transcatheter aortic valve replacement (TAVR). [...]

4. Secukinumab – Dermatitis exfoliative generalised (EPITT no 19354)

Summary of product characteristics

4.8. Undesirable effects

Skin and subcutaneous disorders

Rare: Exfoliative dermatitis [2)]

[2)] Cases were reported in patients with psoriasis diagnosis

Package leaflet

4. Possible side effects

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

- […]
- redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis)

5. Sulfasalazine – Interference with dihydronicotinamide-adenine dinucleotide / dihydronicotinamide-adenine dinucleotide phosphate (NADH/NADP) reaction assays (EPITT no 19351)

Summary of product characteristics

4.4. Special warnings and precautions for use

[…]

Please see Section 4.4 "Interference with laboratory testing".

[…]

Interference with laboratory testing

Several reports of possible interference with measurements, by liquid chromatography, of urinary normetanephrine causing a false-positive test result have been observed in patients exposed to sulfasalazine or its metabolite, mesalamine/mesalazine.

Sulfasalazine or its metabolites may interfere with ultraviolet absorbance, particularly at 340 nm, and may cause interference with some laboratory assays that use NAD(H) or NADP(H) to measure ultraviolet absorbance around that wavelength. Examples of such assays may include urea, ammonia, LDH, α-HBDH and glucose. It is possible that alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatine kinase-muscle/brain (CK-MB), glutamate dehydrogenase (GLDH), or thyroxine may also show interference when sulfasalazine treatment is given at high doses. Consult with the testing laboratory regarding the methodology used. Caution should be exercised in the interpretation of these laboratory results in patients who are receiving sulfasalazine. Results should be interpreted in conjunction with clinical findings

4.5. Interaction with other medicinal products and other forms of interaction

[…]

~~Several reports of possible interference with measurements, by liquid chromatography, of urinary normetanephrine causing a false-positive test result have been observed in patients exposed to sulfasalazine or its metabolite, mesalamine/mesalazine.~~

Package leaflet

2. What you need to know before you take sulfasalazine

Tell your doctor if you are taking or have recently taken [Product name], or any other sulfasalazine containing products, because they may affect results of blood and urine tests.

6. Temozolomide – Drug reaction with eosinophilia and systemic symptoms (DRESS) (EPITT no 19332)

Summary of product characteristics

4.8. Undesirable effects

Tabulated list of adverse reactions

Skin and subcutaneous tissue disorders

Frequency 'not known': Drug reaction with eosinophilia and systemic symptoms (DRESS)

7. Topiramate – Uveitis (EPITT no 19345)

Summary of product characteristics

4.8. Undesirable effects

Eye disorders

Frequency not known: uveitis

Package leaflet

4. Possible side effects

Tell your doctor, or seek medical attention immediately if you have the following side effects:

Frequency not known (cannot be estimated from the available data):

- Inflammation of the eye (uveitis) with symptoms such as eye redness, pain, sensitivity to light, runny eyes, seeing small dots or getting blurred vision