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EMA/PRAC/397088/2018
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 11-14 June 2018 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. Nabumetone – Drug reaction with eosinophilia and systemic symptoms (DRESS) (EPITT no 19241)

Summary of product characteristics

4.4. Special warnings and precautions for use

Serious skin reactions, ~~some of them fatal~~, including exfoliative dermatitis, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported ~~very~~ rarely in association with the use of NSAIDs, including nabumetone (see section 4.8).

At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, nabumetone should be withdrawn immediately and an alternative treatment considered (as appropriate).

Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first two months of treatment. Nabumetone should be discontinued at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity.

If the patient has developed a serious reaction such as SJS, TEN or DRESS with the use of nabumetone, treatment with nabumetone must not be restarted in this patient at any time.

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



4.8. Undesirable effects

Summary of safety profile

Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with nabumetone treatment (see section 4.4).

Table of ADRs

Skin and subcutaneous tissue disorders

Very rare: Bullous reactions including toxic epidermal necrolysis, Stevens Johnson syndrome, drug reaction with eosinophilia and systemic symptoms, erythema multiforme, angioedema, pseudoporphyria, alopecia

Package leaflet

4. Possible side effects

Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (drug reaction with eosinophilia and systemic symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using <medicine> if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

2. Varenicline – Loss of consciousness (EPITT no 19146)

Summary of product characteristics

4.7. Effects on ability to drive and use machines

CHAMPIX may have minor or moderate influence on the ability to drive and use machines.

CHAMPIX may cause dizziness, somnolence and transient loss of consciousness, and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.

4.8. Undesirable effects

Nervous system disorders

[...]

Not known Transient loss of consciousness

Package leaflet

2. What you need to know before you take CHAMPIX

Driving and using machines

CHAMPIX may be linked with ~~produce~~ dizziness, sleepiness and transient loss of consciousness. You should not drive, operate complex machinery or engage in any other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

4. Possible side effects

- Not known
 - o Transient loss of consciousness