



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 6-9 July 2015 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. Dexlansoprazole; esomeprazole; lansoprazole; omeprazole; pantoprazole; rabeprazole – Subacute cutaneous lupus erythematosus (EPITT no 18119)

Summary of Product Characteristics (both prescription and non-prescription)

Section 4.4 - Special warnings and precautions for use

Subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping {Drug name}. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

Section 4.8 - Undesirable effects

Skin and subcutaneous tissue disorders

Frequency 'not known': Subacute cutaneous lupus erythematosus (see section 4.4).



Package Leaflet (both prescription and non-prescription)

Section 2: What you need to know before you take {Drug name}

Warnings and precautions

Talk to your doctor before taking {Drug name}:

- if you have ever had a skin reaction after treatment with a medicine similar to {Drug name} that reduces stomach acid.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with {Drug name}. Remember to also mention any other ill-effects like pain in your joints.

Section 4: Possible side effects

- Frequency 'not known': rash, possibly with pain in the joints

2. Donepezil – Rhabdomyolysis (EPITT no 18261)

Summary of Product Characteristics

Section 4.8 - Undesirable effects

Musculoskeletal, connective tissue and bone disorders

Frequency 'very rare': Rhabdomyolysis*

(To be inserted in the table footnote): * Rhabdomyolysis has been reported to occur independently of neuroleptic malignant syndrome and in close temporal association with donepezil initiation or dose increase.

Package Leaflet

Section 4: Possible side effects

Serious side effects:

You must tell your doctor immediately if you notice these serious side effects mentioned. You may need urgent medical treatment.

- Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis).