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Pharmacovigilance Risk Assessment Committee (PRAC)

# New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 29 November-2 December 2021 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. Olmesartan; olmesartan, amlodipine; olmesartan, hydrochlorothiazide; olmesartan medoxomil, amlodipine besilate, hydrochlorothiazide – Autoimmune hepatitis (EPITT no 19258)

**Summary of product characteristics**

4.8. Undesirable effects

Tabulated list of adverse reactions (for fixed-dose combinations in the column relating to olmesartan mono-substance):

Hepatobiliary disorders

Frequency not known: Autoimmune hepatitis*

Case description below the tabulated summary of adverse reactions:

*Cases of autoimmune hepatitis with a latency of few months to years have been reported post-marketing, that were reversible after the withdrawal of olmesartan.

[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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**Package leaflet**

4. Possible side effects

Section below the heading dealing with serious side effects requiring immediate action/medical attention:

[...] the following ~~two~~ side effects can be serious:

[...]

Frequency not known: If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with X longer time ago, **contact your doctor immediately** who will evaluate your symptoms and decide on how to continue your blood pressure medication.