



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 6-9 July 2020 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. Lisdexamfetamine – QT prolongation and cardiac arrhythmia (EPITT no 19533)

Summary of product characteristics

4.4. Special warnings and precautions for use

Cardiovascular adverse events

Hypertension and other cardiovascular conditions

Lisdexamfetamine has shown to prolong the QTc interval in some patients. It should be used with caution in patients with prolongation of the QTc interval, in patients treated with drugs affecting the QTc interval, or in patients with relevant pre-existing cardiac disease or electrolyte disturbances.

4.8. Undesirable effects

Tabulated list of adverse reactions

Cardiac disorders

QTc prolongation; Frequency not known

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



Package leaflet

2. What you need to know before you take <product name>

Warnings and precautions

Talk to your doctor or pharmacist before using <product name> treatment if you have:

- family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances

Tell your doctor or pharmacist if any of the above applies to you before starting treatment. This is because <product name> can make these problems worse. Your doctor will want to monitor how the medicine affects you.

<Product name> may cause heart rhythm disorders in some patients. If you experience palpitations or irregular heartbeat during the period of treatment, you should inform your doctor immediately. The risk of heart problems may increase with increase of the dose. Therefore, the recommended dosage should be followed.

4. Possible side effects

Some side effects could be serious. If you get any of the side effects below, see a doctor straight away:

Not known: frequency cannot be estimated from the available data

- Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on an electrocardiogram).
See section 2, Warnings and precautions.

2. Tumour necrosis factor alpha inhibitors: adalimumab; certolizumab pegol; etanercept; golimumab; infliximab – Kaposi’s sarcoma (EPITT no 19480)

Summary of product characteristics

4.8. Undesirable effects

Neoplasms benign, malignant and unspecified (including cysts and polyps)

Frequency not known: Kaposi’s sarcoma

Package leaflet

4. Possible side effects

Not known (frequency cannot be estimated from the available data): Kaposi’s sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi’s sarcoma most commonly appears as purple lesions on the skin.