22 October 2015
EMA/PRAC/661880/2015
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 5-8 October 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~~.

Anakinra – Thrombocytopenia (EPITT no 18337)

Summary of Product Characteristics:

Section 4.8 – Undesirable effects:

Blood and lymphatic system disorders

Frequency 'common': thrombocytopenia

Thrombocytopenia

In clinical studies in RA and CAPS patients, thrombocytopenia has been reported in 1.9% of treated patients compared to 0.3% in the placebo group. The thrombocytopenias have been mild, i.e. platelet counts have been >75 x10^9/l.

During post-marketing use of Kineret, thrombocytopenia has been reported, including occasional case reports indicating severe thrombocytopenia (i.e. platelet counts <10 x10^9/l).

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Package Leaflet:

4. Possible side effects

Common side effects (may affect up to 1 in 10 people):

- Thrombocytopenia (low level of blood platelets).