18 May 2017
EMA/PRAC/252868/2017
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 2-5 May 2017 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. Brentuximab vedotin – Cytomegalovirus (CMV) reactivation (EPITT no 18789)

Summary of product characteristics

4.4. Special warnings and precautions for use

Serious infections and opportunistic infections

Serious infections such as pneumonia, staphylococcal bacteraemia, sepsis/septic shock (including fatal outcomes) and herpes zoster, Cytomegalovirus (CMV) (reactivation) and opportunistic infections such as Pneumocystis jiroveci pneumonia and oral candidiasis have been reported in patients treated with brentuximab vedotin. Patients should be carefully monitored during treatment for the emergence of possible serious and opportunistic infections.

4.8. Undesirable effects

Infections and infestations

Frequency 'uncommon': Cytomegalovirus infection or reactivation

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Package leaflet

4. Possible side effects

Uncommon side effects (affects less than 1 in 100 people)

- new or recurring cytomegalovirus (CMV) infection