



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 April 2016
EMA/PRAC/259913/2016
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 11-14 April 2016 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~~.

Olanzapine – Drug reaction with eosinophilia and systemic symptoms (DRESS) (EPITT no 18534)

Summary of Product Characteristics

Section 4.8. Undesirable effects

Skin and subcutaneous tissue disorders

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (frequency unknown)

Package Leaflet

4. Possible side effects

Very rare side effects include serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia).

