



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/PRAC/43845/2025
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 10-13 February 2025 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 on the webpage for [PRAC recommendations on safety signals](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Mogamulizumab – Colitis (EPITT no 20113)

Summary of product characteristics

4.8 Undesirable effects

Gastrointestinal disorders

Frequency 'common':

Colitis

Description of selected adverse reactions

Gastrointestinal disorders

Colitis was mainly characterized by watery diarrhoea, in some cases excessive.

Package leaflet

4. Possible side effects

Serious side effects

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



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

- Watery diarrhoea, more bowel movements than usual, severe abdominal pain or tenderness which are possible signs of inflammation of the large bowel (colitis).