3 May 2021[1]
EMA/PRAC/199753/2021
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 6-9 April 2021 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. Azathioprine – Erythema nodosum (EPITT no 19623)

Summary of product characteristics

4.8. Undesirable effects

Immune system disorders

Several different clinical syndromes, which appear to be idiosyncratic manifestations of hypersensitivity, have been described occasionally following administration of azathioprine tablets and injection. Clinical features include general malaise, dizziness, nausea, vomiting, diarrhoea, fever, rigors, exanthema, rash, erythema nodosum, vasculitis, myalgia, arthralgia, hypotension, renal dysfunction, hepatic dysfunction and cholestasis (section 4.8 - Hepatobiliary disorders).

[…]

Package leaflet

4. Possible side effects

[…]

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
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• allergic reactions, (these are uncommon side effects which may affect up to 1 in 100 people) the signs may include:

[…]

- redness of the skin, skin nodules or a skin rash (including blisters, itching or peeling skin)

[…]