



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2023¹
EMA/PRAC/416581/2023
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 25-28 September 2023 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. Azacitidine (injectable formulations) – Cutaneous vasculitis (EPITT no 19929)

Summary of product characteristics

4.8 – Undesirable effects

Skin and subcutaneous tissue disorders

Frequency 'not known': Cutaneous vasculitis

Package leaflet

4 - Possible side effects

Not known (frequency cannot be estimated from the available data)

Inflammation of blood vessels in the skin which may result in rash (cutaneous vasculitis)

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

