



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 8-11 February 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. Prednisolone²; prednisone² – Bradycardia (EPITT no 19613)

Summary of product characteristics

4.8. Undesirable effects

Cardiac disorders

Frequency 'not known': Bradycardia*

*Following high doses

Package leaflet

4. Possible side effects

Not known: Slow heart rate

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

² For systemic use.

