

PRARMACEVICAL COMPANIES OF Johnson Johnson

## RATIONALE OF THIS DOCUMENT

The purpose of this piece is to outline the following for each class of biologic treating PsA:

- Special warnings and precautions for use as per Section 4.4 of the SmPC.
- Patient groups for whom the product is contraindicated, or for whom caution is advised.
- Main safety risks for each drug class were selected from section 4.4 of the SmPC (Special warnings and precautions for use). Risks qualified as "rare" or "isolated" were still included if they had a dedicated sub-section in section 4.4.
- For the section "to avoid in patients with", section 4.3 (Contraindications) of the SmPC was evaluated.
- For the section "to be used with caution in patients with", sections 4.4 of the SmPC was evaluated.
- Only risks, contraindications, special warnings and precautions common to all drug SmPCs within the class were included. If these differed between drugs of the same class, these were specified in the footnotes.
- An exception was permitted when all drugs except one within the class included the same risk, contraindication, special warning or precaution; a footnote was added for the exception.
- For drug classes with only two biologics treating PsA, any risk, contraindication, special warning and precaution mentioned in one but not the other drug SmPC was not included in the main text, and only specified in the footnotes.
- Recommendations for discontinuations were not included as only recommendations/ contraindications prior to initiation were of interest in this piece.

PsA: Psoriatic Arthritis; SmPC: Summary of Product Characteristics.

