

OFF-LABEL DRUG PRESCRIBING: SAFETY, EVIDENCE, AND ETHICS - A LITERATURE REVIEW

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RESUMO

This work presents a literature review on off-label drug prescribing, defined as the use of approved medicines for indications, doses, populations, routes, or frequencies not included in official labeling. The review synthesizes recent evidence on efficacy, safety, ethical aspects, and regulatory implications across dermatology, psychiatry, neurology, and cardiovascular medicine. Based on selected MEDLINE/PubMed studies, it discusses how off-label prescribing may be clinically necessary in specific contexts, while remaining associated with relevant uncertainties when supporting evidence is limited or heterogeneous. The work highlights the importance of individualized benefit-risk assessment, shared decision-making, documentation of scientific rationale, appropriate monitoring, and pharmacovigilance.

Palavras-chave: Uso Off-Label; Efeitos Colaterais E Reações Adversas Relacionados A Medicamentos; Medicina Baseada Em Evidências; Ética Médica; Farmacovigilância.