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perspectives.

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Sommario/riassunto

This monograph gathers and evaluates data on adverse events (AEs) associated specifically with those “biomedicines” – monoclonal antibodies, fusion proteins, and cytokines – that have recently entered therapeutic use in humans. All AEs observed when using each member of this new drug class are covered, with a view to improving understanding of pathogenesis, facilitating prevention, monitoring, and control, and contributing to the development of better drugs that provide benefits while minimizing risk. Further aspects here examined include the role of drug mechanisms of action and immunogenicity in relation to AEs outcome and induction of systemic syndromes. Additional data on AEs in off-label treatments are also considered. Electronic data sheets, downloadable from the Springer Extra Materials platform, include more detailed safety data as well as additional basic information on product characteristics, pre- and post-marketing AEs classified according to frequency, and system/organ targeting. Data on excipients and selected information on drug interactions and associations are also provided. Adverse Events with Biomedicines: Prevention Through Understanding will serve as a detailed, practical guideline to this important new area, which demands the attention of clinicians, immunologists, oncologists, allergologists, public health professionals, and drug companies.

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