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# Drug adverse events associated with temozolomide administration: A real-world pharmacovigilance study using the FAERS database from 2014 to 2024

Wenpei Chen [1], Deji Wu [1], Xianjun Chen [1]

Affiliations

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## Abstract

BackgroundTemozolomide, an alkylating agent with antitumor effects, is commonly used to treat newly diagnosed glioblastoma multiforme (GBM) and recurrent or progressive GBM or anaplastic astrocytoma. As its usage has increased, so have reports of associated adverse events (AEs), though these AEs have not been systematically documented. Pharmacovigilance plays a key role in assessing the benefits and risks of drugs.ObjectiveTo systematically identify AEs associated with temozolomide through analysis of data from the FDA Adverse Event Reporting System (FAERS) in real-world settings.ResultsA total of 11,400 reports identified temozolomide as the primary suspect drug, leading to the identification of 200 AE signals. These AEs were linked to 27 system organ classes (SOCs), with the top five being general disorders and administration site conditions (n = 5151, ROR = 1.18), injuries, poisonings, and procedural complications (n = 2825, ROR = 0.98), blood and lymphatic system disorders (n = 2375, ROR = 6.32), gastrointestinal disorders (n = 2254, ROR = 1.08), and nervous system disorders (n = 2084, ROR = 1.05). New suspected AEs, such as mutagenic effects, aspergillosis, and intracranial hemorrhage, were identified, which were not listed in the drug's package insert. The majority of AEs (n = 758) occurred within the first month of use, though some were reported up to a year after treatment (n = 126).ConclusionsThese findings provide valuable insights for optimizing temozolomide use and minimizing its potential side effects, enhancing its safety in clinical practice.

**Keywords:** FAERS; Temozolomide; adverse events; pharmacovigilance; real-world study.