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Research Article

# Descriptive analysis of valsartan-related adverse events reported in the FAERS database

Nehad Jaser Ahmed*

[1]Department of Clinical Pharmacy, College of Pharmacy, Prince Sattam Bin Abdulaziz University, Alkharj, Saudi Arabia. ORCID ID: 0000-0003-4215-6225,

Email: n.ahmed@psau.edu.sa.

## Abstract

The Food and Drug Administration (FDA)-approved angiotensin II receptor blocker valsartan can treat hypertension in adults and children one year of age and up, decrease heart failure hospitalizations, and improve post-myocardial infarction (MI) survival. For a broad range of people, including diabetics, the elderly, kids, and high-risk cardiovascular patients, it is safe and effective. In addition to causing less coughing than angiotensin-converting enzyme (ACE) inhibitors, common side effects like headache, nausea, and dizziness are similar to those of the placebo. Reports containing valsartan as the primary suspect medication that were submitted before April 1, 2025, and that were obtained from the FDA Adverse Event Reporting System (FAERS) database using the generic name "valsartan" are included in the analysis. Only reports that included all relevant information (drug name, adverse event, and patient data) were taken

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into consideration. Adverse events were categorized using the Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms. In the FDA Adverse Event Reporting System (FAERS) there were 36,323 adverse events (AEs) related to valsartan. High blood pressure was the most common adverse event associated with valsartan (13.38%). The next in order were dizziness (6.39%), therapeutic ineffectiveness (5.81%) and dyspnea (5.17%). This FAERS data analysis indicates that there is a possibility of side effects of using valsartan, such as headache, dizziness, hypertension, ineffectiveness, and dyspnea. These results underscore the importance of dosage and monitoring particularly in high-risk patients.

**Keywords:** adverse events; FDA Adverse Event Reporting System (FAERS); Food and Drug Administration (FDA); valsartan; hypertension; angiotensin II receptor blockers.

## 1. Introduction

Hypertension (HTN) is currently diagnosed when diastolic blood pressure (DBP) exceeds 80 mm Hg and/or systolic blood pressure (SBP) exceeds 130 mm Hg. Hypertension is one of the most widespread chronic diseases that can be defined by a constant high level of arterial pressure and is one of the significant causes of heart failure, stroke, myocardial infarction, and renal failure. The updated practice guidelines suggest treating patients with a persistent blood pressure of 140/90 mmHg, with a therapeutic goal of 130/80 mmHg. The definition and management of hypertension, however, have changed. Although most cases are idiopathic (essential hypertension), excessive salt consumption has long been recognized as a significant risk factor [1].

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Antihypertensives include angiotensin II receptor blockers (ARBs), ACE inhibitors, calcium channel blockers, and thiazide diuretics. The choice of medication is influenced by age, race, and comorbidities; ACE/ARBs are advised for kidney disease or heart failure. Beta-blockers are not advised as first-line treatment unless specific indications are met. Combination therapy is used if monotherapy doesn't work (e.g., ACE/ARB with CCB or diuretics). For resistant hypertension, medications like spironolactone, loop diuretics, or vasodilators are used [2]. Angiotensin II receptor blockers (ARBs), a popular class of antihypertensive medications, function by selectively blocking angiotensin II's ability to bind to the type 1 receptor [3]. This reduces aldosterone release, encourages vasodilation, and lowers blood pressure. Diabetic nephropathy, hypertension, and congestive heart failure are among the chronic renal diseases for which ARBs are prescribed. ARBs often work better for people who experience ACE inhibitor-related side effects, such as angioedema or a persistent cough, even though their therapeutic profiles are similar to those of ACE inhibitors. Although ARBs are usually well tolerated, they can cause dizziness, hypotension, hyperkalemia, and renal impairment [4].

Valsartan, a well-known ARB, has been approved by the FDA to treat hypertension in adults and children aged ≥1 year, reduce heart failure hospitalization rates, and improve post-myocardial infarction survival in some heart failure patients [5]. It has proven to be safe and helpful for a variety of populations, including children, the elderly, diabetics, and people with high-risk cardiovascular conditions. Common adverse effects (AEs) linked to valsartan include fatigue, headache, nausea, and dizziness, and they occur at rates comparable to those of a placebo. It's interesting to note that valsartan had a lower incidence of cough than ACE inhibitors [6].

Adverse events (AEs) affect at least 10% of patients, posing a significant problem in medical practice. These adverse effects can be caused by drugs, treatments, or other interventions, which can be simple to manage side effects or life-threatening issues [7]. Post-marketing surveillance plays a critical role in detecting long-term or rare side effects, as during pre-approval clinical trials only a small number of participants are typically enrolled (only a few thousand). The FDA is assisted by the Adverse Event Reporting System (FAERS), which collects and analyzes information about producers, customers and medical professionals [8-11]. This research is aimed at investigating and outlining the negative experiences with the use of valsartan that are documented in the FAERS database due to the high prevalence of the drug.

## 2. Materials and Methods

This retrospective pharmacovigilance study examined adverse event (AE) reports involving valsartan from the FDA Adverse Event Reporting System (FAERS) database. FAERS is an important post-marketing surveillance program that gathers voluntary reports from manufacturers, healthcare providers, and patients to identify possible medication safety signals [10].

Records containing valsartan as the main suspect drug were analyzed before April 1, 2025. The generic name "valsartan" was used to retrieve these reports from the FAERS database. Only reports with complete information (drug name, adverse event, and patient data) were taken into consideration, and adverse events were categorized using MedDRA Preferred Terms. Duplicate submissions, incomplete submissions, and submissions received after April 2025 were not included.

The data was summarized using descriptive statistics. AEs were measured as percentages and frequencies (counts). (Part / Whole) × 100 was the formula used to determine the rate for each group or category. This formula uses "Whole" to display the total number of reports and "Part" to display the reported numbers in a category. The database known as the FDA Adverse Event Reporting System (FAERS) is open to the public. To access or use this data for research, no special authorization or ethical approval is needed.

## 3. Results

The FDA Adverse Event Reporting System (FAERS) contained 36,323 reports of adverse events (AEs) related to valsartan. After eliminating 14,397 cases with an unspecified age, the patient age distribution was examined, yielding 21,926 evaluable reports, as indicated in Table 1. Of these, adults aged 65–85 years accounted for the highest percentage of adverse events (54.3%), followed by those aged 18–64 years (36.2%).

**Table 1**. The age of patients who had adverse events.

| Category | Number of Cases | Percentage |
|---|---|---|
| 0-1 Month | 91 | 0.41 |
| 2 Months-2 Years | 40 | 0.18 |
| 3-11 Years | 21 | 0.09 |
| 12-17 Years | 119 | 0.54 |
| 18-64 Years | 7939 | 36.19 |
| 65-85 Years | 11909 | 54.30 |
| More than 85 Years | 1807 | 8.24 |
| Totals | 21926 | 100.00 |

To examine gender-specific trends, 3,281 cases with unspecified gender were omitted, resulting in 33,042 reports available for evaluation. The analysis indicated that female patients (57.8%) encountered adverse events more often than male patients (42.2%) (Figure 1).

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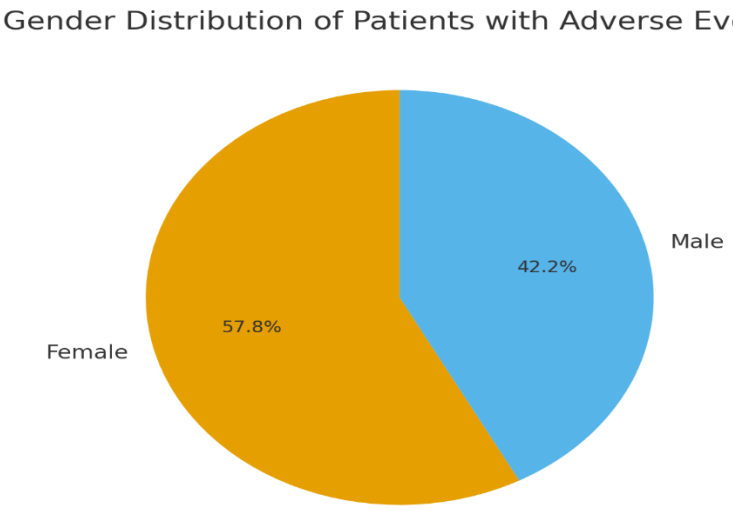


**Figure 1**. The gender of patients who had adverse events.

For reporter-specific analysis, 1,501 occurrences with unspecified reporter status were removed, leaving 34,822 evaluable reports. The data revealed an almost equal distribution between healthcare professionals (49.2%) and consumers (50.8%), with consumers filing slightly more reports than professionals (Table 2).

**Table 2.** The specialty of the reporters.

| Category | Number of Cases | Percentage |
|---|---|---|
| Healthcare Professional | 17,111 | 49.2 |
| Consumer | 17,711 | 50.8 |
| Totals | 34,822 | 100.00 |

The most common adverse events linked to valsartan were as follows: elevated blood pressure (4861 reports, 13.38%), dizziness (2320 reports, 6.39%), therapeutic ineffectiveness (2111 reports, 5.81%), headache (1859 reports, 5.12%), acute kidney injury (1759 reports, 4.84%), fatigue (1621 reports, 4.46%), hypotension (1596 reports, 4.39%), and malaise (1477 reports, 4.07%), as shown in Figure 2.

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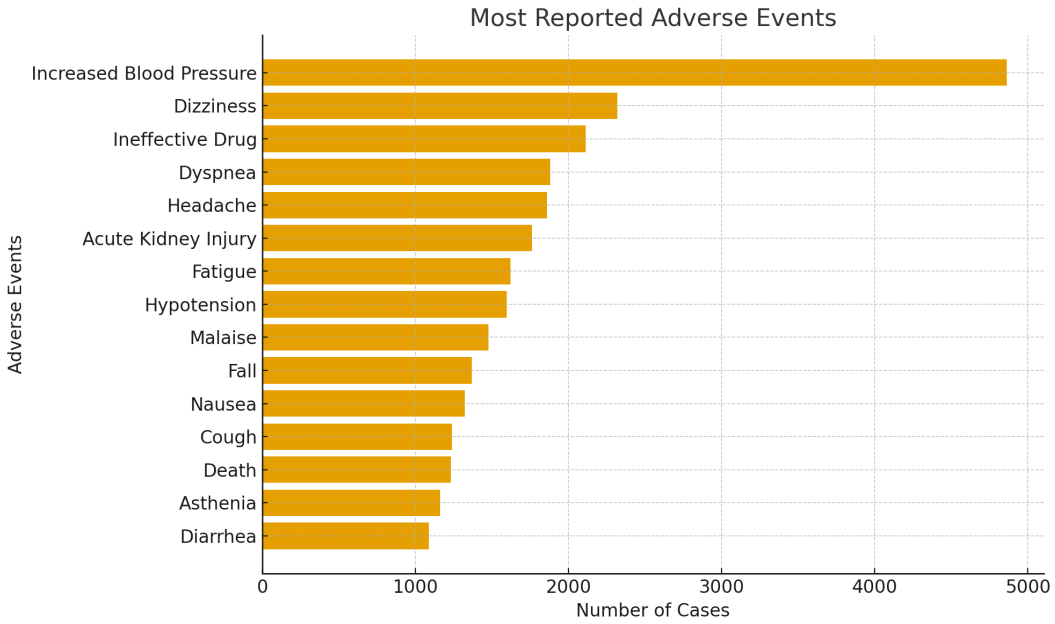


**Figure 2**. The most reported adverse events.

## 4. Discussion

Using data from the FDA Adverse Event Reporting System (FAERS) database, the main goal of this study was to thoroughly assess and describe adverse drug reactions (AEs) associated with the medication valsartan. The age distribution of reported adverse events was noteworthy, with the highest incidence occurring among middle-aged adults (18–64 years) and those aged 65–85 years. This discrepancy is in line with epidemiological evidence showing that age-related pharmacokinetic changes, polypharmacy, and a higher burden of comorbidities increase the likelihood of adverse events in older patients [12-14]. In particular, valsartan's metabolism and excretion may be impacted by age-related changes in hepatic and renal function, which could increase the risk of toxicity. The identified bias is further compounded by the fact that older adults are more likely to receive valsartan due to their high prevalence of cardiovascular disease

and hypertension. Older patients with multiple chronic conditions who use several medications are more likely than younger patients to experience adverse drug events (ADEs). Because valsartan is commonly used with other antihypertensives, diuretics, or heart failure medications, drug interactions and cumulative side effects may increase the risk of adverse events in this vulnerable group [12-14].

In this post-marketing analysis, hypertension was the most commonly reported adverse event (AE); however, valsartan medication was associated with several AEs. Fatigue (8.6%), headache (11.9%), dizziness (18.2% of all reports), acute renal failure (9.3%), and therapeutic ineffectiveness (15.7%) were the most common adverse events that were reported. Such results are congruent with the safety profile of the UK National Health Service (NHS) which indicates that more than 1% of patients treated experience a headache (19%), nausea (15%), vomiting (8%), diarrhea (6%), dizziness (22%), and musculoskeletal pain (5%), among other adverse effects [15]. Chen et al.'s cardiovascular safety analysis brought to light more severe cardiac complications, especially in patients who already had coronary artery disease [16]. Among the cases were notable arrhythmias (4.5%), cardiogenic shock (1.8%), angina exacerbations (2.7%), and new-onset heart failure (3.2% of cases). Despite these adverse event profiles, valsartan has a good safety-efficacy ratio, according to large clinical trials. The overall incidence rates of adverse events (AEs) in studies involving hypertension (38.5%) are comparable to those in placebo groups (36.2%), while they are marginally higher in populations with heart failure (42.1% vs. 39.8%) [17]. The results from Fogari and Zoppi's work, indicating similar rates of adverse events (pediatric: 28.4% and diabetic: 37.6% cohorts; older patients: 41.3%; younger patients: 39.1%), support the acceptability of valsartan in specific populations [6]. The most common adverse effects (such as fatigue, 12.1%; headache, 14.7%; nausea, 9.8%; and dizziness,

18.3%) showed no statistically significant difference compared with placebo ($p > 0.05$). A significant decrease in cough cases (valsartan 1.2% vs. lisinopril 8.7%; $p < 0.001$) showed that valsartan was much better than ACE inhibitors and thus preferable for individuals who cough regularly [6]. Generally, these results suggest that the risk-benefit ratio of valsartan remains positive in most indications and subgroups of patients without any irrespective restrictions to its use due to its measurable adverse effect.

One of the effective indicators used to treat heart failure, high blood pressure, and heart attacks is Valsartan, which is a common medication. Among the adverse conditions that it can cause are dizziness, headaches, exhaustion, high blood pressure, acute kidney damage, and, in extreme cases, serious cardiac issues such as heart failure and cardiac arrhythmia, to mention a few. Most of the side effects are similar to those of a placebo and are mild. Careful monitoring is necessary for some patient groups, though, such as those with kidney issues or a higher risk of heart disease. Regular blood pressure checks, kidney function tests, and electrolyte monitoring are recommended by healthcare providers, particularly for high-risk patients. By doing this, risks will be reduced. Hughes et al. emphasized the importance of using up-to-date baseline data to monitor performance and adjust tactics. To do this, healthcare organizations need to implement comprehensive systems for the systematic collection, processing, and exchange of data. Automated tracking and reporting technology can significantly improve real-time performance tracking [18]. Patients should be asked to report any severe or ongoing symptoms, such as edema, dizziness, or an irregular heartbeat. Additionally, caution should be used when taking valsartan with other antihypertensive medications to prevent sharp drops in blood pressure. Valsartan is a medication that is generally safe and effective, but it can be made even safer and more effective with individualized treatment and careful observation.

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## Strengths and Limitations

This study uses the FDA Adverse Event Reporting System (FAERS), one of the largest publicly available pharmacovigilance datasets, to assess the adverse event (AE) profile of valsartan in real-world scenarios. The main advantage of this method is its ability to analyze large volumes of diverse patient data in various clinical settings, which facilitates the identification of potential safety indicators that might not be found in controlled clinical trials. However, like other spontaneous reporting systems, FAERS has some inherent limitations that should be acknowledged. Underreporting bias is a significant concern because minor or well-established adverse events are less likely to be reported. Furthermore, if duplicates are not properly handled, they may make some negative events seem more frequent. Temporal reporting biases, such as an increase in submissions following media coverage or drug safety alerts, may also affect how data is interpreted. It should be noted that although FAERS provides useful AE correlations, there is no concrete evidence linking valsartan to reported responses. Another major drawback is the inability to calculate actual incidence rates because of a lack of denominator data (such as the total number of patients exposed to valsartan).

Despite these limitations, the study provides useful details about the safety profile of valsartan, highlighting the importance of continuing pharmacovigilance and educating physicians about its potential risks. The findings demonstrate how important it is to combine FAERS data with prospective research in order to precisely determine incidence and causality in real-world settings. To better understand the safety profile of valsartan, future research should combine spontaneous reporting methods with reliable data sources, such as electronic medical records, prescription databases, and carefully planned prospective cohort studies. This holistic approach

would allow for a more comprehensive assessment of risks in the real world. Particular attention should be paid to vulnerable patient groups, such as children, the elderly, and patients with neurological disorders, to better characterize their particular risk factors. Furthermore, the application of advanced analytics, like machine learning algorithms, on real-world data has the potential to revolutionize pharmacovigilance by facilitating the early detection of safety signals and implementing more targeted risk-reduction techniques. These advancements would significantly increase our ability to anticipate and prevent dangerous drug reactions in clinical settings.

## 5. Conclusion

According to the FAERS database, this descriptive analysis shows a high risk of adverse events associated with the use of valsartan. The most common side effects that were reported were headache, dizziness, high blood pressure, ineffectiveness of treatment, and dyspnea. These findings highlight the importance of careful prescribing of valsartan at the appropriate dosage, particularly in individuals who are highly at risk. Medical professionals are advised to exercise caution to contain and mitigate any negative impact.

## List of Abbreviations

**AE**: Adverse event

**FAERS**: FDA Adverse Event Reporting System

**HTN**: Hypertension

**SBP**: Systolic blood pressure

**DBP**: Diastolic blood pressure

**ARBs**: Angiotensin II receptor blockers

**ACE**: angiotensin-converting enzyme

## Ethics approval and consent to participate

Since this study is based on a synthesis of the literature and does not involve human participants, animals, or original data collection, ethical approval and consent to participate are not applicable.

**Author Contributions**

Nehad Jaser Ahmed is the sole author of the manuscript and is responsible for writing and review as well as its conceptualization, methodology, investigation, formal analysis, data curation, and visualization. Author has reviewed and accepted the published version of the paper

**Consent for publication**

Not applicable.

**Availability of data and material**

The data analyzed in this study were obtained from the publicly available FDA Adverse Event Reporting System (FAERS) database [11]. The processed data supporting the findings of this study are included in the article. No new data was generated.

**Conflicts of Interest**

The author declares no conflicts of interest regarding this manuscript.

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ChatGPT and DeepSeek Artificial Intelligence (AI) tools were only utilized to help with grammar refining and language editing.

Author confirms that no parts of the manuscript were generated using AI tools. AI assistance was used only for paraphrasing and language refinement of text that was originally written by the authors. No AI tool was employed to generate new scientific content, data interpretation, or original text in the manuscript.

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