International Journal of Pharmaceutical Research and Development

ISSN Print: 2664-6862
ISSN Online: 2664-6870
Impact Factor: RJIF 8.55
IJPRD 2025; 7(2): 699-703
www.pharmaceuticaljournal.net
Received: 02-08-2025
Accepted: 07-09-2025

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Self-medication and omeprazole misuse: Implications for pharmacovigilance

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DOI: https://www.doi.org/10.33545/26646862.2025.v7.i2h.233

Abstract
Self-medication has become increasingly prevalent across global populations, driven by easy access to pharmaceuticals and the desire for quick symptom relief. Among the drugs frequently utilized without professional consultation, omeprazole, a widely available proton pump inhibitor (PPI), is particularly notable due to its efficacy in managing common gastric acidity. However, the prolonged and unsupervised misuse of omeprazole can lead to significant adverse drug reactions (ADRs) and serious long-term complications, including nutrient deficiencies and renal injury. Crucially, these drug-related safety issues are often under-reported, resulting in weak or delayed safety signals. Effective pharmacovigilance (PV) is therefore essential to detect harmful consumption patterns, encourage patient reporting, and improve overall patient safety. This article critically evaluates the current self-medication practices involving omeprazole, assesses its associated short- and long-term risks, and highlights the implications for pharmacovigilance in mitigating these challenges. Better regulation of over-the-counter (OTC) availability, robust patient education, and enhanced healthcare involvement are urgently necessary to prevent complications linked to long-term PPI misuse.

Keywords: Self-medication practices, unsupervised drug use, over-the-counter (OTC) availability

1. Introduction
Self-medication refers to the use of therapeutic agents by individuals to treat perceived symptoms or conditions without seeking professional guidance from a registered healthcare practitioner. This practice has become globally rampant, particularly accelerated by modern lifestyle changes, chronic stress, irregular dietary habits, and the pervasive influence of readily available health-related content on the internet and social media platforms. The immediate desire for relief, coupled with the assumption of safety regarding non-prescription drugs, fuels this trend across both developed and developing nations [1].

Among the pharmacological classes frequently implicated in self-medication, Proton Pump Inhibitors (PPIs) stand out. PPIs, such as omeprazole, are highly effective in suppressing gastric acid secretion and are prescribed for conditions like peptic ulcer disease and gastroesophageal reflux disease (GERD). However, due to their potent and rapid-acting ability to relieve the discomfort of acidity, omeprazole is widely available and often assumed by the public to be harmless, leading to widespread misuse.

This assumption is critically flawed. The unsupervised continuation of omeprazole therapy beyond the recommended short-term duration exposes patients to a spectrum of risks. These dangers include the development of significant nutrient deficiencies (such as Vitamin B_{12} and magnesium), the progression of kidney-related complications like acute interstitial nephritis, and increased susceptibility to gastrointestinal infections [2]. Furthermore, prolonged symptomatic relief can inadvertently mask serious underlying diseases, delaying the diagnosis of potentially fatal conditions like gastric cancer or complicated peptic ulcers.

The current challenge lies in the fact that when a drug is consumed outside the standard prescribing environment (i.e., through self-medication), any resulting Adverse Drug Reactions (ADRs) are rarely documented or reported to regulatory authorities. This lack of documentation weakens the safety signals surrounding the drug. Therefore, Pharmacovigilance (PV)-the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem-becomes

critically essential. Strong PV mechanisms are required to effectively capture these hidden risks and ensure patient safety within the context of increasing self-medication practices.

The present review critically discusses the evolving scenario and potential health consequences of the self-medication and misuse of omeprazole. It further analyzes the various associated short- and long-term complications and emphasizes the need for robust pharmacovigilance strategies and regulatory interventions to safeguard public health against the hazards of prolonged PPI misuse.

2. About Omeprazole

Omeprazole is a foundational member of the Proton Pump Inhibitor (PPI) class of medications. It functions as a potent and long-lasting inhibitor of gastric acid secretion by selectively targeting the H^+/K^+ ATPase enzyme system-commonly referred to as the "proton pump"-located on the secretory surface of the parietal cells in the stomach [3]. By irreversibly blocking this final step of acid production, omeprazole achieves profound and sustained acid suppression.

In clinical practice, omeprazole is correctly indicated for short-term management of conditions such as active duodenal and gastric ulcers, erosive esophagitis, and as part of regimens to eradicate *Helicobacter pylori*. The standard therapeutic guidelines recommend its use for specific, finite durations, typically 4 to 8 weeks, depending on the diagnosed condition [4].

However, the widespread availability, combined with the perception of its rapid symptomatic efficacy, has driven its significant off-label and non-prescribed use. Individuals frequently initiate therapy for mild or transient symptoms of dyspepsia or heartburn. Moreover, due to the high recurrence rate of acidity upon cessation ("acid rebound"), many users feel compelled to continue the medication indefinitely. This cycle transforms a necessary short-term treatment into a long-term self-medicated regimen, significantly deviating from established clinical guidelines and laying the groundwork for potential adverse outcomes. The primary driver for this misuse is the quick relief it provides without the perceived inconvenience and cost of a medical consultation.

3. Self-Medication Overview: The practice of self-medication is not a homogenous phenomenon; it varies significantly based on socio-economic, cultural, and regulatory environments [5]. The scenario related to PPIs, particularly omeprazole, reflects broader trends influenced by public health literacy and pharmaceutical availability.

3.1 Global and Indian Scenario

Globally, the self-administration of non-prescription medication has witnessed a sharp increase, partially due to the reclassification of various therapeutic agents, such as some PPIs, from prescription-only (Rx) to over-the-counter (OTC) status in several countries. The increasing prevalence of lifestyle-related ailments, particularly chronic stress-induced acidity, means that individuals are managing symptoms rather than seeking underlying diagnoses. In countries like India, the self-medication scenario is characterized by a high prevalence of gastric complaints and the comparatively easy accessibility of pharmaceutical products. PPIs frequently rank among the top drugs consumed without a formal prescription [6].

3.2 Reasons for Self-Medication of Omeprazole

The specific choice of omeprazole for self-treatment is often driven by a combination of psychological, practical, and economic factors. These reasons contribute directly to its misuse pattern:

- **Fast Relief:** Omeprazole provides immediate and powerful acid suppression, leading to quick symptomatic relief.
- **Perceived Safety:** The public often harbors a misleading belief that omeprazole is "totally safe" for long-term consumption.
- **Convenience and Cost-Saving:** Self-medication bypasses the time, effort, and expense associated with a clinical consultation.
- **Continuation of Old Prescriptions:** Patients who were initially prescribed the drug for a short course often continue the regimen long after the underlying condition is resolved [7].
- **Repeat Purchases:** Medical stores frequently allow repeat purchases without requiring a renewed prescription.

Driving Factor	Description of Factor	Consequence on Misuse Pattern
Easy Accessibility	OTC status in many regions and lax enforcement of prescription rules at retail pharmacies.	Facilitates repeated and prolonged purchase without medical guidance.
Perceived Safety (Misleading Belief)	Long-standing presence in the market leads the public to believe it is harmless, even with chronic use.	Encourages patients to continue the medication indefinitely, ignoring duration guidelines.
Symptom Suppression (Fast Relief)	Potent and rapid acid-suppressing effects immediately alleviate discomfort (heartburn, acidity).	Patients prioritize immediate relief over diagnostic investigation or specialist consultation.
Cost and Convenience	Self-medication avoids the time, travel, and consultation fees associated with formal healthcare visits.	Leads to patient reluctance to seek professional advice when symptoms return or persist.
Continuation Bsias	Patients continue taking the drug after the prescribed course ends, especially if 'acid rebound' occurs upon stopping.	Directly contributes to the transition from appropriate short-term treatment to dangerous long-term misuse.
Lifestyle Acidity	High prevalence of stress, irregular meals, and diet-induced acidity leads to chronic symptomatic self-treatment.	Normalizes the daily intake of a PPI for minor, chronic symptoms that should be managed by lifestyle changes.

4. Omeprazole Safety Profile: Risks of Long-Term Misuse: The prolonged use of omeprazole, particularly in the context of self-medication where regular monitoring is absent, carries a high risk of systemic complications that extend beyond simple gastrointestinal effects.

4.1 Short-term Adverse Drug Reactions (ADRs)

Acute use of omeprazole is generally well-tolerated, but common, non-serious ADRs are frequently reported [8]:

- **Gastrointestinal:** Headache, nausea, flatulence, and abdominal pain.
- **Neurological:** Occasional reports of dizziness.

4.2 Long-term Complications

The chronic suppression of gastric acid, necessary for vital biological processes, significantly increases the risk of serious complications [9].

4.2.1 Nutrient Deficiency

Reduced gastric acidity impairs the absorption and bioavailability of several essential micronutrients:

- **Vitamin B_{12} (Cobalamin) Deficiency:** Acid is crucial for releasing Vitamin B_{12} from food proteins. Long-term PPI use can lead to B_{12} malabsorption, potentially resulting in peripheral neuropathy and macrocytic anemia [10].
- **Magnesium (Hypomagnesemia):** Chronic PPI use has been linked to severe hypomagnesemia, which may manifest as cardiac arrhythmias, muscle weakness, and seizures.
- **Iron Deficiency:** Impaired gastric acid production can reduce the absorption of non-heme iron.

4.2.2 Kidney Injury

PPIs have been increasingly linked to severe renal issues:

- **Acute Interstitial Nephritis (AIN):** This idiosyncratic hypersensitivity reaction is a known PPI complication, often leading to acute kidney injury (AKI).
- **Chronic Kidney Disease (CKD) Progression:** Large-scale observational studies suggest a statistically significant association between long-term PPI use and the development or progression of CKD, independent of other risk factors [11].

4.2.3 Infections

The suppression of gastric acid raises the gastric pH level, fundamentally altering the natural defense mechanism against ingested pathogens [12]:

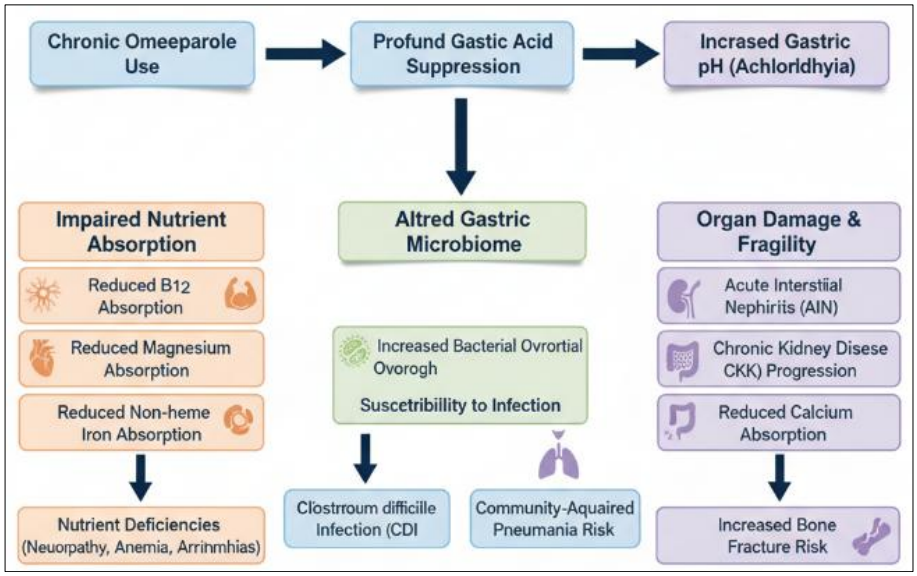
- ***Clostridium difficile* Infection (CDI) and Diarrhea:** The altered gut flora and reduced acid barrier increase susceptibility to *C. difficile* overgrowth.
- **Pneumonia Risk:** PPI use may increase the risk of community-acquired pneumonia due to the potential for microbial colonization of the upper gastrointestinal tract [13].

4.2.4 Bone Health Issues

Reduced calcium absorption due to low acidity can negatively impact bone mineral density. Chronic use of PPIs is associated with an increased risk of hip, spine, and wrist fractures, particularly in older adults [14].

4.2.5 Masking of Serious Diseases

The most critical non-pharmacological risk of self-medication is the symptomatic relief that delays the diagnosis of serious underlying pathologies, such as gastric or esophageal cancers [15].



5. Pharmacovigilance Concepts and Challenges

5.1 The Role of Pharmacovigilance (PV)

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem [16]. Its fundamental purpose is to continuously monitor the safety profile of medicines once they are approved and marketed, ensuring that the benefits of the drug continue to outweigh the risks.

5.2 Why PV is Essential for Self-Medicated Drugs

The primary challenge posed by self-medication is the reporting gap. When drugs are obtained and consumed without a prescription, there is no formal record of use or physician involvement. Consequently, any resulting ADRs-especially the insidious, long-term complications like B_{12} deficiency or CKD progression-are rarely reported to national PV centers [17]. This leads to a significant underestimation of the drug's true risk profile in real-world settings, resulting in:

- **Delayed Safety Signals:** Regulatory bodies receive inadequate data, delaying necessary safety interventions or label updates.
- **Weak Causality Assessment:** Without clinical documentation, assessing the causal link between the drug misuse and the adverse event becomes difficult.

5.3 PV Tools and Database Utilization

PV systems employ several tools to detect and analyze safety signals:

- **Spontaneous Reporting Systems:** These utilize standardized forms (e.g., the Yellow Form in India, or similar forms globally) submitted by healthcare professionals and increasingly by patients.
- **Causality Assessment Scales:** Tools like the Naranjo Algorithm help determine the probability that an ADR was caused by the drug [18].
- **Global Databases:** The WHO-Uppsala Monitoring Centre (UMC) manages the VigiBase, a global database where safety signals concerning PPIs (such as links to renal injury and hypomagnesemia) are actively tracked, providing essential global context for national regulators.

5.4 PPI Safety Signals in the PV Landscape

The long-term risks associated with PPIs were largely identified post-marketing through robust pharmacovigilance and pharmacoepidemiology studies. The discovery of the link between chronic PPI use and events like *C. difficile* infection and acute interstitial nephritis prompted label changes and safety warnings globally. This success highlights the power of PV, but the current misuse scenario requires the PV system to adapt to non-traditional data sources, including pharmacist interventions and patient self-reporting, to capture the hidden burden of ADRs.

5.4.1 The Indispensable Role of the Pharmacist in Mitigating PPI Misuse

Pharmacists, as the most accessible healthcare professionals, occupy a critical position in the monitoring and management of self-medication, particularly for OTC drugs like omeprazole. Their role extends far beyond dispensing and is vital for filling the reporting gap created by unsupervised drug use.

6.1 Point-of-Sale Patient Counseling

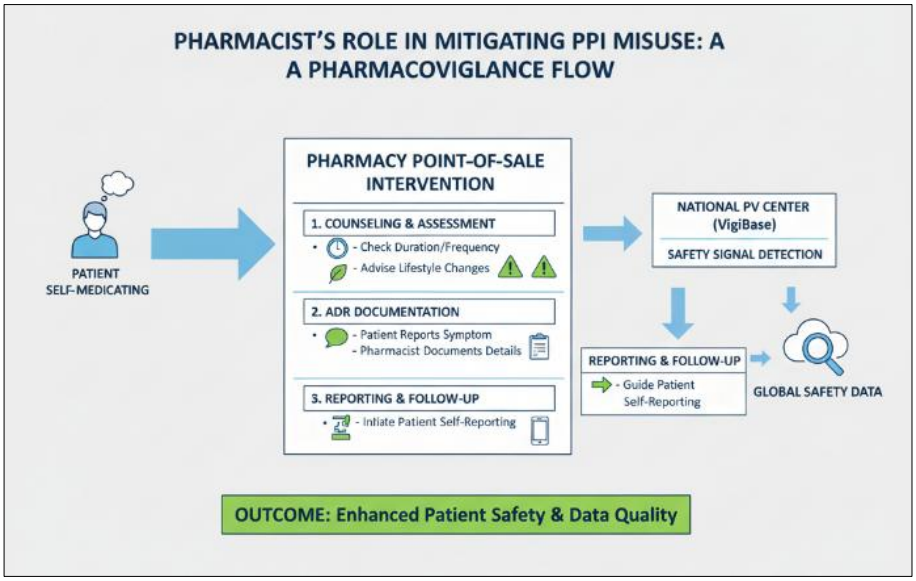
Pharmacists must implement mandatory, brief counseling for every repeat PPI purchase [19]:

- **Checking Inappropriate Use:** Systematically questioning the patient on the duration and frequency of omeprazole use, and the specific symptoms being treated. If use exceeds 2 weeks without a physician consultation, the patient should be strongly referred.
- **Advising on Lifestyle Changes:** Providing actionable, non-pharmacological advice regarding diet, stress, and meal timing as the primary management strategy for mild or transient acidity.
- **Informing on Risks:** Clearly communicating the risks of long-term use, particularly the signs of nutrient deficiencies and the danger of masking serious illnesses.

6.2 Active ADR Documentation and Reporting

The pharmacist can transform passive self-medication into an active PV event:

- **Documentation of Suspected ADRs:** If a patient reports a symptom while self-medicating, the pharmacist should be trained to attribute the symptom to the PPI, document the details of the drug's use, and initiate a formal report.
- **Facilitation of Patient Reporting:** Pharmacists should be primary advocates for patient self-reporting, guiding users on how to submit ADRs directly to the national PV center using simplified forms or digital tools.



7. Regulatory and Public Health Recommendations

To effectively address the systemic issue of omeprazole misuse and the resulting PV challenges, coordinated interventions across regulatory, public health, and educational sectors are necessary.

7.1 Regulatory and Supply-Chain Interventions

- **Limit OTC Availability of PPIs:** Authorities should re-evaluate the current OTC status of PPIs, potentially restricting the sale of large pack sizes or high-dose formulations without a prescription to enforce short-term use.
- **Mandatory Enhanced Warning Labels:** Pharmaceutical manufacturers must be mandated to include highly visible, explicit warnings on OTC packaging detailing the serious risks of long-term use (e.g., "Risk of Kidney Damage and Bone Fracture after 4 weeks") and a clear maximum duration of self-treatment [20].
- **Training and Audits for Retail Pharmacies:** Regulatory bodies must enforce stricter checks on retail

pharmacies to prevent repeat dispensing of PPIs without prescription, coupled with mandatory PV training programs for all dispensing staff.

7.2 Public Health and Awareness Campaigns

- **Targeted Social Media Awareness Campaigns:** Launching engaging, evidence-based campaigns across social platforms to specifically target young adults and working professionals who rely heavily on self-medication.
- **College-Level PV Awareness Activities:** Integrating practical pharmacovigilance concepts and the dangers of self-medication into health and science curricula at the college level to foster responsible drug use habits [21].
- **Encouraging Direct Patient Reporting:** Simplifying and widely advertising national PV reporting systems, providing QR codes on drug leaflets and pharmacy posters that link directly to the patient reporting form.

8. Conclusion

The escalation of self-medication practices, particularly involving readily available and seemingly benign drugs like omeprazole, has created a substantial and often hidden public health crisis. Prolonged and unsupervised use of this PPI transcends simple acidity relief, leading to major complications including severe nutrient deficiencies, kidney injury, and heightened infection risk. The resulting under-reporting of adverse drug reactions severely compromises the integrity of existing safety databases. This emphasizes the critical importance of Pharmacovigilance (PV), which must adapt by leveraging the role of the pharmacist and implementing patient-centric reporting tools. Moving forward, tighter regulations on OTC sales, mandatory, explicit warnings, and comprehensive awareness campaigns targeting the public are necessary to curb the hazards of long-term PPI misuse and secure patient safety.

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