



A Comprehensive Review of Over-the-Counter (OTC) Medications: Benefits, risks, misuse, and regulatory perspectives

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Abstract

Over-the-counter (OTC) medications, also known as non-prescription drugs, are widely used for managing a variety of minor and self-limiting conditions without a physician's prescription. While OTC medications enhance healthcare accessibility, reduce costs, and empower patient self-care, they are not without risks. This review explores the various dimensions of OTC drug use, including classification, therapeutic benefits, misuse and abuse patterns, safety considerations in specific populations such as children and pregnant women, and pharmacist interventions. The document highlights the potential for adverse effects, drug interactions, and public misconceptions regarding the safety of OTC products. Furthermore, it discusses strategies adopted by pharmacists and healthcare systems to mitigate misuse, alongside the growing influence of digital platforms in promoting OTC products. This comprehensive overview underscores the importance of informed use, education, and regulatory oversight in ensuring the safe and effective use of OTC medications.

Keywords: OTC medications; Self-medication; Drug misuse; Pharmacist intervention; Patient safety; Public awareness

1. Introduction

Over-the-counter (OTC) medications, commonly referred to as non-prescription medications (NPMs), are medications that are available from licensed healthcare providers without a prescription. Over-the-counter medications are commonly used to treat a variety of minor illnesses. They can be easily acquired from neighborhood pharmacies, as well as other retail establishments like supermarkets and gas stations. They are also increasingly being bought online. Due to their proven safety and efficacy after prolonged clinical usage, over-the-counter medications encourage self-care, which benefits patients as well as health care systems by lessening the strain on other healthcare settings [1]. OTC medications, like traditional prescription medications, can have negative side effects and, because of their active ingredients, can be abused and misused [2]. Through self-treatment, patients are able to recognize their own diseases and select the appropriate medication from the pharmacy to treat their symptoms. In order for patients to self-treat, they must have access to over-the-counter (OTC) medications. Many medications that are now marketed over-the-counter (OTC) were formerly categorized as prescription medications. Pharmaceutical companies can research what influences patient's choices of pharmaceutical goods for specific therapeutic segments and take advantage of this to increase over-the-counter sales [3]. They are frequently used to treat a wide variety of mild ailments, such as heartburn, musculoskeletal pain, headaches, and colds. OTC medications have a comforting safety record, but they are not innocuous, and abusing them that is, using them for nonclinical purposes can result in serious side effects like addiction and even death. Negative clinical outcomes can also result from the misuse of over-the-counter medications, which happens when these medications are taken for legitimate medical reasons but in the incorrect way [4]. Over-the-counter (OTC) analgesics, such as aspirin, ibuprofen, and paracetamol, are frequently used to treat pain, including headaches, fever, musculoskeletal discomfort, and menstrual cramps. If taken as directed, they are harmless; nevertheless, abuse

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has been linked to illnesses such gastrointestinal tract infections and hypertension. Without a formal prescription, many people utilize over-the-counter (OTC) medications as their first line of therapy since they are inexpensive and available from tiny pharmacies, street sellers, and friends and family. Drugs can be obtained without a doctor's prescription or authorization, which speeds up treatment and eases the strain on the healthcare system. However, over-the-counter medications can lead to adverse effects, drug toxicity, drug-drug interactions, and drug-disease contraindications, as well as the waste of medical resources if not utilized, as advised [5]. The main function of over-the-counter (OTC) products is as an adjuvant for the treatment and maintenance of acne. Skin cleansers, moisturizers, and sunscreens are a few examples of relevant over-the-counter items. In addition to lowering oiliness, redness, inflammation, pain, and discomfort, these products may also improve skin texture, the amount of scarring, the time it takes for lesions to heal, and maybe the frequency and intensity of acne flare-ups. OTC products may affect treatment results since many acne patients have been known to attempt several over-the-counter (OTC) medications before seeking medical help, and they frequently continue to use them while undergoing prescription therapy [6]. But it's also important to take into account unintentional exposure brought on by misunderstandings over the proper administration route. The more packets sold, the higher the chance of harmful exposure. In the case of over-the-counter (OTC) medications, television advertising campaigns may contribute to the rise in the quantity of units dispensed by pharmacies [7]. Depending on the drug type, dosage, length of therapy, gestational age, and the time between maternal administration and delivery, some over-the-counter medications may have negative effects on HDP even though the majority have an excellent safety profile. Other medications may have unproven safety or are known to negatively affect the fetus. Preeclampsia is more likely to occur in women who took acetaminophen throughout the third trimester of pregnancy. Aspirin and NSAID use during pregnancy have been shown to raise the chance of miscarriage. Pregnant women who take NSAIDs run the risk of developing embryo-fetal and neonatal side effects because they pass the placenta. NSAID use during the first trimester of pregnancy is linked to an increased risk of miscarriage and birth defects. On the other hand, NSAID exposure after 30 weeks of pregnancy is linked to a higher risk of oligohydramnios and early closure of the fetal ductus arteriosus [8]. Although OTC NSAID use is seven times higher than prescribed NSAID use due to the perception that NSAIDs are safe medications, their use is linked to serious gastrointestinal tract problems, the most prevalent of which is upper gastrointestinal tract (UGIT) hemorrhage. NSAID users had a 2.7–3 times higher overall risk of UGIT hemorrhage than non-users [9]. In several nations, codeine is sold over-the-counter. Codeine overdose symptoms are largely similar to those of ordinary opioid poisoning; nevertheless, non-opioid analgesics are frequently used with the substance when it comes to over-the-counter versions. Among all psychoactive compounds, cough treatments are among the most abused, not just in the OTC drug category. Though non-opioid dextromethorphan and zipeprol also received some attention as recreational drugs due to their hallucinogenic effects when taken in supratherapeutic amounts, the misuse of antitussives is frequently linked to the aforementioned opioids, such as codeine or dihydrocodeine. Zipeprol has subsequently been discontinued due to a number of deadly poisoning instances. Nonetheless, cough medications containing dextromethorphan continue to be among the most widely used antitussive medications globally [10]. Because OTC/POM misuse is linked to a rise in mental health problems, risky behaviors, and a decline in quality of life, it is critical that efficient therapies be offered as soon as possible. Due to variances in the drug market and the accessibility of medications, people's features may differ throughout nations. They may also differ when compared to those who primarily use illegal street drugs [11]. Additionally, OTC abuse has been linked to noteworthy medication combinations, impacts on one's physical and mental health, individual differences in reaction, and a substantial economic impact on users, their families, and the community at large. At the moment, surveys and clinical records (such as case reports and case series) provide the majority of OTC misuse data [12]. Abuse of over-the-counter medications is found in several countries, and although the products utilized differed, five key categories appeared: Codeine-containing medications include cough syrups, particularly those containing dextromethorphan, sedative antihistamines, decongestants, laxatives, and complicated analgesics. Although OTC drugs allow people to treat self-limiting diseases without seeking medical assistance, there are health hazards associated with this supply system because it is commonly believed that OTC medications are generally safe [13].

2. OTC drugs

OTC drugs are pharmaceuticals that, in accordance with national laws, can be sold to customers directly without a prescription. Over-the-counter (OTC) drugs are mostly used as a first-line/initial therapeutic method for a variety of minor and self-limiting diseases, such as allergies, musculoskeletal discomfort, headaches, heartburn, and the common cold. The safety and effectiveness of any medication are the primary factors considered when choosing one from the over-the-counter (OTC) category. With an emphasis on consumers awareness, education, and socioeconomic level, the World Health Organization (WHO) has deemed self-medication to be an essential component of the changing healthcare system [14].

3. Basic details about over-the-counter medications

Prescriptions are not necessary for medications that are sold to people over-the-counter (OTC). Many conditions and their symptoms, including pain, colds and coughs, constipation, diarrhea, acne, and more, are treated by over-the-counter (OTC) drugs.



Figure 1 Basic information of OTC Medication

4. Types of OTC medicines

There are many different types of over-the-counter drugs. Brand names are susceptible to change, and store brands are widely used. Read the labels to learn what the active components are in any product. Types of over-the-counter medications include:

4.1. Antihistamine

These help sneezing, itchy eyes, and runny noses caused by allergies (but not colds). Some might make your children sleep. These should not be used by children younger than two. Only use with a doctor's permission in newborns or kids who have asthma. These drugs include diphenhydramine, chlorpheniramine, and loratadine.

4.2. Cough suppressants

These prevent the body from coughing. Coughing is required to clear the lungs of mucus and microorganisms. Before administering a cough suppressant to your child, should speak with a healthcare provider.

4.3. Decongestants

These can relieve congestion caused by allergies or colds. They accomplish this by narrowing the inner parts of the nose to make breathing easier. They should never be used for longer than two or three days at a time. Numerous negative effects are possible with oral decongestants. These include experiencing dizziness, restlessness, and agitation.

4.4. Antidiarrhea

These drugs are frequently unnecessary. Take your child to the doctor if they have diarrhea. Remember to drink plenty of water with your children. See your child's healthcare provider before administering these drugs. Children under the age of 19 should not be given any medication that contains bismuth subsalicylate. Children younger than two should not be given loperamide-containing medications.

4.5. Laxatives

These can relieve constipation. They operate in different ways. Some people add water or fiber to their excrement to make it more solid. This may facilitate the movement of the intestines. Some are applied to the stool's surface to make it slicker. Some soften the feces, making them easier to pass. Others cause the intestines to move more forcefully. Infants

and children should never be given laxatives without first speaking with their physician. Laxatives include glycerin suppositories, magnesium hydroxide, psyllium, and mineral oil.

5. Safety of OTC Medication

There are several fields that require OTC medication safety, including:

- OTC medication safety during pregnancy.
- Safety of Children's Over-the-Counter Medication.
- Safety of Over-the-Counter Drugs in Emergencies [15].

5.1. OTC medication safety during pregnancy

Since paracetamol is thought to be the safest and mildest painkiller with the fewest teratogenicity risks, doctors actually advise pregnant women to take it to treat typical pregnancy symptoms. In 2005, the FDA designated paracetamol as a "Pregnancy Category B" medication. This category can be created for substances for which "no adequate and well-controlled studies have been conducted in pregnant women and animal reproduction studies have failed to demonstrate a risk to the fetus." Since significant amounts of paracetamol have been found in fetal plasma samples, often at levels that match those found in the mother's liver, it has long been recognized that the drug may easily cross the placenta. More generally, the majority of NSAIDs are placenta-transparent. Thus, in addition to paracetamol, other analgesics and their metabolites may also directly affect the growing fetus [16].

5.2. Safety of Children's Over-the-Counter Medication

Many of the same painful problems that affect adults also affect children, such as headaches, sprains and strains, dental pain, symptoms of the flu and cold, and pain following vaccinations. Since weight has been demonstrated to have a greater impact on pharmacokinetics and, in turn, systemic exposure than age, it is best to base the dosage used for children on their weight rather than their age in order to prevent dosing errors and ensure optimal safety. Age-based doses are still provided by certain standards, though. Children should take oral NSAIDs and acetaminophen for all common painful diseases, but at smaller amounts than adults. It is advised that both drug classes be used in conjunction if either is insufficient when taken alone, as in the case of youngsters experiencing postoperative or dental pain, for instance. One French guideline recommends acetylsalicylic acid for children with migraines; however, all other guidelines caution against using it in children under the age of 12 or 16 (depending on the guideline) due to the possibility of Reye's syndrome, especially if the child is recuperating from a viral infection [17].

5.3. Safety of Over-the-Counter Drugs in Emergencies

The main goal of treating colds and coughs is to temporarily alleviate symptoms while letting the illness progress. However, research has shown negative consequences linked to the improper use of over-the-counter cough and cold remedies. Reports indicate that the use of cough and cold medications has a considerable risk of death, despite the fact that the majority of overdoses are not deadly. Over 1500 children under the age of two were admitted to emergency rooms over the course of two years due to side effects linked to the usage of over-the-counter cough and cold remedies. Young children are more likely to experience adverse effects, dosage mistakes, and overdosing due to their higher annual frequency of colds. Concerns about the safety of over-the-counter cough and cold drugs, including reports of mortality in youngsters exposed to these medications, prompted a label revision in 2008 [18].

6. Requirements for being categorized as an over-the-counter medication

A medication product must fulfill the following broad requirements in order to be categorized as over-the-counter:

- The medication has been thoroughly investigated, used extensively in clinical settings, and is time-tested;
- Adverse drug reaction monitoring has demonstrated that the drug product contains an active ingredient or ingredients with demonstrated safety and efficacy (large margin of safety and high therapeutic index) even in the absence of expert supervision; and
- Neither the Dangerous Drugs Board (List A) nor the International Narcotics Control Board (INCB) have designated the drug product as [an] internationally restricted drug product, nor does it [have] a bioequivalence problem (List B) [19].

7. Classification of over the counter drugs

OTC drugs approved by FDA are:

- NSAIDs, antacids, antidiarrheal, antihistamines & allergy products, antimicrobials, antiperspirants
- Bronchodilators & antiasthmatics
- Cold remedies, contraceptives & vaginal products
- Dandruff & athlete's feet, dentifrices & dental products
- Emetics & antiemetics
- Laxatives
- Ophthalmics
- Sunburn treatments & sunscreens
- Vitamins & minerals [20].

8. Benefits of using approved OTC medicines

OTC medications make it easier and less expensive for the general public to receive treatment for mild or self-limiting conditions. Additionally, GPs have more time to address more significant health issues because they are not required to provide prescriptions for trivial diseases. For nations like India, where the doctor-to-patient ratio is lower (1:1800) than in other nations, this is quite helpful. By using their professional experience to educate patients, pharmacists can provide a crucial interface for assuring the best possible use of over-the-counter medications [21].

9. Examples of Some OTC Drugs and Their uses

Table 1 OTC drugs & their uses [22]

Sr. No.	OTC drugs	Uses
1	Antacids (e.g., Tums, Rolaids, Mylanta)	Stomach upset, Heartburn.
2	Antidiarrheal medicine (e.g., Kaopectate, Imodium A-D, Pepto-Bismol).	Diarrhea.
3	Antihistamines (e.g., Chlor- Trimeton, Benadryl).	Allergies. Alleviation of cold symptoms. Reduces itching.
4	Cough suppressant (e.g., Robitussin-DM or others with dextromethorphan).	Dry cough without mucus.
5	Decongestant (e.g., Sudafed, Dimetapp).	Stuffy and runny nose. Postnasal drip. Allergies. Fluid in the ears.
6	Expectorant (e.g., Robitussin or others with guaifenesin).	Cough with mucus.
7	Laxatives (e.g., Ex-Lax, Correctol (stimulant types), Metamucil (bulk-forming type)	Constipation.
8	Throat anesthetic (e.g., Sucrets, Chloraseptic spray).	Minor sore throat.
9	Toothache anesthetic (e.g., Anbesol).	Toothache. Teething.
10	Acetaminophen (e.g., Tylenol, Anacin-3, Datril, Liquiprin, Panadol, Tempa).	Relieves discomfort. Reduces fever. Does not lessen edema.
11	Aspirin (e.g., Bayer, Bufferin).	Relieves discomfort. Reduces edema and fever.
12	Ibuprofen (e.g., Advil, Motrin, Adult and Children's Advil). Ketoprofen for adults (e.g., Actron, Orudis KT). Naproxen Sodium for adults (e.g., Aleve).	Relieves discomfort. Reduces edema and fever.

10. Abuse

Many over-the-counter drugs have the potential to be abused. Antihistamines, sleep aids, caffeine, ephedrine, pseudoephedrine, expectorants and antitussives, dextromethorphan, laxatives, anabolic steroids, and sildenafil are among the drugs that are frequently abused. High doses of antihistamines are used for euphoria, and laxatives are abused for weight loss. Opiate-based combo medicines including cough/cold medications that contain dextromethorphan, sleep aids, antihistamines, analgesics, hypnotics, and laxatives have been identified as potentially abusive based on global studies on OTC pharmaceutical misuse. The most commonly misused drugs are pain relievers and cough remedies [23].

11. Misuse

Medication "misuse" refers to the improper use of over-the-counter drugs. The improper use of over-the-counter medications for a known medical condition is known as misuse. The extent of the problem of OTC medication abuse is hard to determine, although numerous studies show that the majority of community pharmacists acknowledge that abuse occurs. The term "misuse" will be used by the researchers in this study to describe the inappropriate use of over-the-counter drugs. OTC drug users abuse over-the-counter drugs for a variety of reasons, according to Pharmacy Magazine. Attempts to alter body shape, medicine dependence, inappropriate medical use, accidental misuse, intentional abuse for non-medical purposes (e.g., taking decongestants to boost alertness), and to promote the use of illegal substances are all included.

12. Safe use

If taken improperly, over-the-counter (OTC) medications can be just as dangerous as prescription drugs. Therefore, it is crucial to utilize over-the-counter drugs safely. One of the main forms of malpractice that occur in medical facilities is the improper administration of medications [24].

13. Pharmacists actions to control OTC medication overuse and misuse

- Pharmacists explained how they use consumer behaviors, attitudes, and established protocols to spot instances of overuse or abuse. According to the majority of pharmacists, abusers or misusers could be immediately identified by their physical attributes, behaviors during talks, and facial expressions.
- A lot of pharmacists also believed that frequent visits, making the same product request, requesting a lot at once, going to the pharmacy during peak hours, taking advantage of the crowd to avoid being asked, and refusing any other option were all common behaviors that helped identify instances of misuse and abuse.
- A small percentage of pharmacists reported that some patients tell them about the medication's illegal use.
- When asked how they identify problematic use of over-the-counter medications, almost half of pharmacists mentioned the pharmacy mnemonics WWHAM (which stands for five questions).
- W = Who is the patient?
- W= What are the symptoms?
- H = How long have the symptoms been present?
- A = Action taken,
- M = Medication being taken [25].

Table 2 Common strategies by Pharmacists to control OTC medication abuse [26]

Specific locations	Strategies initiated by pharmacists
Pharmacy	1. A decline in sales of the implicated over-the-counter drugs 2. Report the suspicious behavior of the patient abusing over-the-counter medication to other pharmacies right away. 3. Notifying customers that things were sold out 4. Preventing medicines by concealing the supply 5. Only administering little doses of medicine
Patient Participation	1. Counseling patients of possible misuse of over-the-counter drugs 2. Spreading knowledge about patient advice via the internet and support groups

	3. Distributing informational pamphlets
Involvement of the doctor and other services	1. Offering advice and 2. Getting involved with the doctor 3. Referring to the doctor Employing private clinics' services 4. Making use of specialized services for alcohol and drug misuse

14. Public Awareness, Trends, and the Function of Digital Platforms

Online promotional strategies are now a crucial part of selling over-the-counter (OTC) goods due to the rapid expansion of online platforms and internet penetration. OTC products are ideal for direct-to-consumer marketing because, unlike prescription medications, they may be bought without a doctor's prescription. Due to their increased digital engagement and health consciousness, consumers today frequently look up items and self-care solutions online before making a purchase. This shift opened up new avenues for pharmaceutical firms and health brands to promote their over-the-counter goods through various online marketing platforms [27].

15. Conclusion

OTC medications play a pivotal role in modern healthcare by offering accessible and cost-effective treatment options for a range of minor ailments. However, their easy availability and perceived safety often lead to misuse and abuse, resulting in significant health risks including toxicity, dependency, and drug interactions. Vulnerable populations such as children and pregnant women are particularly at risk. The role of pharmacists is critical in identifying and preventing inappropriate use through patient counseling and monitoring. Regulatory guidelines, public awareness campaigns, and evidence-based digital interventions must be strengthened to ensure the responsible use of OTC medications. A balance between accessibility and safety is essential to harness the full potential of OTC drugs while safeguarding public health.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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