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Review Article

Adverse Drug Reactions Associated with Commonly used Over-the-Counter Medicines: A Comprehensive Review

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ABSTRACT

Over-the-counter (OTC) medicines are widely used for the self-management of common and minor health conditions such as pain, fever, cough, cold, allergy, heartburn, and gastrointestinal disturbances. Their easy accessibility, relatively low cost, convenience, and perceived safety have contributed to their increasing use without consultation with healthcare professionals. However, the risk of adverse drug reactions (ADRs) might be raised by improper self-medications, poor dose, polypharmacy, extended usage, drug interactions, and insufficient information about medications. An overview of popular over-the-counter medications and their side effects is given in this article, with special attention to analgesics, cough and cold remedies, antacids, antihistamines, and some vitamins. When used improperly or in excess, analgesics like paracetamol and non-steroidal anti-inflammatory medicines can result in hepatotoxicity, gastrointestinal issues, renal damage, and other negative consequences. Cough and cold remedies that contain expectorants, decongestants, cough suppressants, and antihistamines may cause side effects such as nausea, drowsiness, sleeplessness, disorientations, and rebound congestion. Gastrointestinal problems, electrolyte imbalance, toxicity in vulnerable people, and clinically significant medication interactions are all possible side effects of antacids. First generation antihistamines in particular can have anticholinergic effects, drowsiness, cognitive impairment, and other negative side effects. Advanced age, polypharmacy, low health literacy, noncompliance with dose directions, underlying medical conditions, and concurrent use of prescription medications, alcohol, or other drugs all raise the risk of OTC-related adverse drug reactions (ADRs). Therefore, even if over-the-counter medications play a significant part in selfcare, using them should be accompanied with sufficient information, suitable dosage, careful reading of pharmaceutical labels, and awareness of potential side effects and drug interactions, promoting the safe and sensible use of over-the-counter medications requires more participation from pharmacists and medical experts as well as public education and pharmacovigilance initiatives.

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INTRODUCTION

Over-the-counter (OTC) medications can be obtained with a prescription from an RMP-registered medical practitioner or, in certain cases, directly from the consumer without a prescription. The term “non-prescription” refers to drugs other than prescription-only medications in INDIA. The Drugs and Cosmetics Act, 1945 Schedule H and Schedule X strictly regulate the prescription drugs and regulate their sale and distribution until it is prescribed by a physician.¹

According to National medical Commission (NMC), OTC refers to drugs used for common minor illness which are available over the counter and are considered safe and effective for public use without the need to consult a healthcare professional. The NMC said OTC drugs can legally be sold without a doctor’s prescription. In the regulations relating to professional conduct of RPM registered medical practitioners, issued on 2nd August,²

The history of self-medication practice from global perspective is very old and has substantial impact in developing countries like India. World health organization has defined the concept of self-medication as the use of medicinal products by the individuals to treat self-recognized disorders or symptoms or continuous use of a medicine prescribed by a physician for chronic or recurrent diseases or symptoms. Self-medication includes obtaining medicines without a prescription, re-using old prescriptions to purchase medicines, sharing medicines with relatives or members of one’s social circle or using leftover medicines stored at home. Therefore, self-medication is an important component of self-care, which can be defined as the primary resource of public health in the health care system. It includes self-medication, non-drug self-treatment, social support in illness, and first aid in everyday life.³

Self-medication (SM) is a common practice in developed and developing countries throughout the world. SM can be a serious problem and can cause several problems, such as negative pharmaceutical reactions, a possible increase in antimicrobial resistance, and can be a waste of resources.⁴ Use of OTC medicines for self-medication is on the rise around the world and is recognized as a public concern. A lack of knowledge may lead to possibly inappropriate use of medication due to self-medication. This may include use for wrong indication and administration of wrong dosages.⁵ The adverse drug reactions and non-compliance to the treatment programs may be directly caused by lack of adequate knowledge about OTC medications⁶.

A majority of the drugs are bought to treat small diseases like headaches, fevers, throat pains, colds, stomach problems, and skin problems.⁷ Over-the-counter drugs assist in the prevention and treatment of various diseases like headaches, cold, musculoskeletal pain, allergies, and heartburn among others.⁵ People use over-the-counter drugs due to easy access, cheap nature, time-saving, and the freedom of treating themselves from minor diseases without involving the healthcare system.¹³

The list of OTC therapeutic categories that have been listed in accordance with the WHO ATC classification includes the following ten classes of medication:

- dermatological,
- cough & cold medication,
- antacids,
- analgesics,
- laxatives,



- antithrombotic medications,
- antihistamines,
- throat medications,
- nasal medications,
- and anti-diarrhoeal medication.⁹

The OTC therapeutic categories that have been named in the NMC regulations are: topical antibacterial preparations, anti-cough preparations, haemorrhoid preparations, preparations for acne, and non-steroidal anti-inflammatory medicines. The list also consists of: antiseptic, analgesic, decongestant, expectorant, aspirin, anti-ulcer, anti-fungal preparations, antihistamines, vasodilator, anti-flatulence agents and smoking cessation drugs.⁸

ANALGESICS:

Pain is one of the most prevalent health problems in the world that affect individuals at all age groups. The common types of pain include headache, fever, musculoskeletal pain, low back pain, dysmenorrhea, and toothache. Low back pain is the leading cause of disability throughout the world, responsible for an estimated 149 million DALYs annually, while tension type headache afflicts an estimated 42% of the world's adult population.⁹ Pain adversely affects the quality of life by diminishing physical functioning, disrupting sleep, reducing social interaction, and psychological wellbeing. In addition, it leads to huge economic costs due to absence from work and poor work performance.¹⁰

OTC analgesics refer to non-prescription pharmacological drugs which have been authorized for the use in short term relief from mild and moderate pain and fever. Some examples

of OTC analgesics include Paracetamol, Ibuprofen, Aspirin and Naproxen.

Acetaminophen (Paracetamol) refers to a centrally acting analgesic and antipyretic used primarily as a first-choice medicine in the treatment of mild and moderate pain.¹¹ Paracetamol is generally considered as a safe drug, but overdose could arise due to uncertainty regarding daily dosage limits and combinations.¹² Paracetamol poisoning accounts for the majority of cases of acute liver failure, particularly in patients with chronic alcohol abuse or underlying liver disease.¹¹

NSAID: Ibuprofen exhibits analgesics, antipyretic and anti-inflammatory properties. Aspirin is an NSAID that antiplatelet activity. Naproxen is a long-acting NSAID often used for dysmenorrhea and musculoskeletal disorders. NSAIDs may inhibit mucosal prostaglandins and cause gastrointestinal toxicity. This increases the risk of bleeding and peptic ulcer disease. Longer use of NSAIDs can prevent the occurring of renal prostaglandins, which can prevent the occurring of renal prostaglandins, which can lead to acute renal damage or the advancement of chronic renal disease¹¹. Aspirin: Ibuprofen can affect the antiplatelet effect of aspirin. Paracetamol enhances the anticoagulant action of warfarin. Paracetamol is believed to be the best first-line painkiller during pregnancy, although a number of NSAIDs have trimester-specific issues.¹²

COLD AND COUGH PREPARATION:

Cough and Cold Symptoms (CCS) are upper respiratory tract diseases that usually consist of sore throat, cough (caused by inflammation of the lower respiratory tract) and nasal obstruction (sometimes with rhinorrhoea). OTC (over-the-counter) medications are often used by parents to treat common children's ailments¹⁴. A sore or



‘scratchy’ throat develops one to three days after the viral infection.¹⁶

The readily available OTC medicines for treating cough and cold have either one of the following components or a combination of any two of the following: decongestant, cough suppressant, antihistamines, expectorants and antipyretics. Parents give their children cough and cold medicines in order to give temporary relief from symptoms caused by upper respiratory tract infection. These symptoms include runny nose, congestion, coughing and fever.¹⁵ OTC medicines that are usually prescribed for treating CCS include paracetamol, pseudoephedrine, dextromethorphan, chlorpheniramine maleate (CTM), phenylephrine, phenylpropanolamine (PPA), guaifenesin or glyceryl guaiacolate, and bromhexine. These drugs may be in a combination of two or more of them, and the effect may be good if used properly¹⁴.

A) DECONGESTANT:

Decongestants are sympathomimetics or stimulators of adrenergic receptors that cause constriction of the blood vessels of the mucous membrane of the respiratory system, thus reducing the edema caused by the inflammation of the mucous membranes.¹⁵

The FDA has two approved oral decongestants that do not need prescriptions; phenylephrine and pseudoephedrine. They are both α -adrenergic agonists that treat nasal congestion by constricting the enlarged blood vessels that cause airway obstruction. The most frequent AEs caused by the two decongestants include trouble sleeping, irritability, and agitation. Pseudoephedrine is known to reduce nasal congestion caused by the common cold. There are topical vasoconstrictive nasal decongestants that come in spray or drop form, and their examples include xylometazoline

and oxymetazoline. Due to their direct application to the affected site, these drugs give quick relief to nasal congestion, which takes place within minutes. Nevertheless, prolonged use causes mucosal irritation and rebound congestion.¹⁶

B) COUGH SUPPRESSANTS:

Suppressants try to reduce the cough response to a normal state in case the reaction exceeds the level necessary for airway protection¹⁸. Dextromethorphan is the ingredient that acts as a cough suppressant in OTC cough preparations, which usually is taken along with the expectorant guaifenesin. Sleepiness, dizziness, nausea, and upset stomach are some of the side effects observed in people who take dextromethorphan. An antihistamine known as diphenhydramine also can act as a cough suppressant for kids.¹⁵

C) EXPECTORANTS:

Expectorants, also called mucus active agents, increase mucus secretions in the respiratory system, hence increasing the volume of fluids in the respiratory tract and reducing the thickness of the mucus.¹⁷ Guaifenesin is an Expectorant, and it is readily available in the OTC market in combination with either Phenylephrine or Dextromethorphan. Like all other medications, the common side effects associated with the use of Guaifenesin are headache, nausea, and vomiting. While there are reports of allergies caused by Dextromethorphan, a compound often used in combination with Guaifenesin, we were not able to come across any cases of allergies caused by Guaifenesin.¹⁹

ANTACIDS:

Heartburn is described as a painful and burning sensation in the chest, behind the breastbone, or at



the top of the abdomen that occasionally radiates towards the throat. It is caused by the flow of gastric acid back up into the food pipe through the lower esophageal sphincter; it is one of the symptoms of gastroesophageal reflux disease (GERD).²⁰

Antacids are one of the frequently used self-prescribed drugs. Antacids contain either calcium carbonate and magnesium and aluminium salts in different combinations or formulations. The mechanism of action of antacids in the stomach is based on partial neutralization of hydrochloric acid in the stomach and inhibition of the enzyme called pepsin. Antacids have been used in duodenal and gastric ulcers, stress gastritis, gastroesophageal reflux disease, pancreatic insufficiency, non-ulcer dyspepsia, bile acid mediated diarrhoea, biliary reflux, constipation, osteoporosis, urinary alkalization and chronic renal failure as phosphate binder.²¹

The consumption of aluminium is linked with a high likelihood of developing toxicity among those suffering from renal failure and babies. These include: Osteopenia, Microcytic anaemia, Neurotoxicity, Osteomalacia, Constipation, Fecal impaction, Nausea, Vomiting, Abdominal cramps, Hypomagnesemia Hypophosphatemia.

Calcium Carbonate: The following side effects occur commonly to those using this class of antacids: Abdominal pain, Anorexia, Constipation, Acid rebound, Nausea, Vomiting, Flatulence, Xerostomia, Headache, Hypercalcemia, Hypophosphatemia, Milk-alkali syndrome.

Antacids have the potential for clinically significant drug interactions with other medications used by a patient. The following are some examples:

- The use of antacids together with acidic medications (for example, digoxin, chlorpromazine, isoniazid) may affect the absorption of these acidic drugs resulting in decreased plasma levels of the drugs with subsequent diminished effectiveness.
- The use of antacids together with some drugs (such as pseudoephedrine, levodopa) may cause increased absorption of these drugs with the potential for causing toxicity due to the increase in the levels of the drugs in the serum.
- Antacids such as magnesium trisilicate and magnesium hydroxide may react with tetracycline and fluoroquinolone antibiotic drugs affecting their absorption and effectiveness.
- Sodium bicarbonate influences the acidity of urine, and therefore, its effect on the excretion of certain drugs through urine. Sodium bicarbonate reduces the excretion of basic drugs (such as amphetamines and quinidine) while increasing the excretion of acidic drugs (aspirin).²²

ANTI-HISTAMINES:

Antihistamines represent a group of drug compounds that reduce symptoms of diseases caused through histaminic action. When treating allergic responses brought on by immunoglobulin E (IgE) and non-IgE, first-generation antihistamines that function as H₁-receptor blockers are advised. These include persistent urticaria and allergic rhinitis. However, in gastroesophageal reflux disease, second-generation antihistamines or H₂-receptor blockers are used to regulate the production of stomach acid. Common Over-the-counter medications include first generation sedatives like diphenhydramine and chlorpheniramine.



Cetirizine, levocetirizine, loratadine, and fexofenadine are the second generation (preferably non-sedating).

H1 first generation antihistamines: Adverse effects include drowsiness, cognitive impairment, and anticholinergic side effects include constipation, dry mouth, blurred vision, and urine retention. Higher dosages may cause delirium, tinnitus, and dizziness. The use of first-generation antihistamines, such as diphenhydramine, in older persons has been restricted due to an increased risk of falls and cognitive problems. Other significant adverse effects in susceptible people include cardiotoxicity and QT prolongation.

H1 second-generation antihistamines: These medications cause very little drowsiness. FDA warnings from 2025 state that stopping cetirizine and levocetirizine after extended treatment causes severe pruritus; decreasing the medication dose is recommended.

H2 antihistamines: These medications are well tolerated; however, cimetidine causes gynecomastia, galactorrhoea, and significant drug interactions mediated by CYP450. GI problems and vertigo are among the side effects; ranitidine was taken off the market due to its potential to cause cancer.²³

VITAMINS:

NIACIN is a freely accessible over-the-counter drug that may be purchased without the presence of medical expert who could provide guidance on how to take it and warn about any potential side effects. In addition to improving lipid profiles, niacin (also known as nicotinic acid or over-the-counter vitamin B3) has been shown to enhance patient outcomes. Niacin-treated patients in the Coronary Drug Project had fewer non-fatal

myocardial infarction recurrences and decreased death rate nine years after the trial's conclusion.²⁴

RISK FACTORS OF OTC MEDICINES RELATED ADR:

There are a number of causes that increase the likelihood of adverse drug reactions from over-the-counter medications. Misuse of over-the-counter medications to treat acute or chronic pain, particularly when using NSAIDs and paracetamol, is one of the main cause of adverse drug reactions (ADRs). Adverse drug reactions can also result from misuse or abuse of several over-the-counter drugs, such as codeine-based painkillers, sedative antihistamines, dextromethorphan (cough suppressants), and loperamide (anti-diarrheals).

These medications can be abused because of the urge to reduce withdrawal symptoms, improve sleep, induce relaxation, have mind-altering effects, or even cause self-harm in certain cases. Other societal and personal risk factors for OTC drug abuse include unemployment, low self-esteem, interpersonal problems, living alone, lack of education, and health literacy. Older individuals are especially susceptible since they typically have many conditions, take multiple medications (polypharmacy), have diminished vision, and have trouble understanding how to take the medication. They are more likely to experience adverse drug reactions (ADRs) if they do not read medication labels and have insufficient understanding about how to take OTC medications.

Some people overstate their symptoms or shop at many pharmacies to obtain over-the-counter drugs. Negative drug interactions and unpleasant reactions can also result from mixing over-the-counter medications with alcohol, illegal narcotics, or prescription medications like benzos or antidepressants.



Risk Factors

- Improper use of painkillers (paracetamol and NSAIDs)
- Abuse of codeine, dextromethorphan, antihistamine, and loperamide
- Low health literacy
- Unhealthy and inadequate knowledge of drug directions
- Low education
- Advanced age and polypharmacy
- Persistent diseases
- Mental health, socio-economic issues
- Concomitant use of OTC drugs with alcohol, recreational and prescribed drugs
- Medicine seeking from different physicians or pharmacists.²⁵

CONCLUSION:

Over-the-counter (OTC) medicines are an essential part of self-care, offering convenient and cost-effective treatment for common ailments. However, improper use, incorrect dosage, prolonged use, and inadequate knowledge can increase the risk of adverse drug interactions (ADRs). Common OTC medicines, such as analgesics, gastrointestinal, renal and other adverse effects, especially when used irrationally or in conjunction with other medications. Older folks, those with polypharmacy, people with chronic conditions, and people with low health literacy are also at higher risk. Minimising medication through patient education, cautious label reading, pharmacist counselling, and knowledge of possible drug interactions.

Additionally, improving pharmacovigilance systems and promoting ADR reporting can increase medication safety. Overall, to guaranty that over-the-counter medications continue to be a secure and useful part of healthcare, it is essential to strike a balance between simple accessibility and responsible usage.

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