



OVER- THE- COUNNTER MEDICINE

¹Rushikesh A. Narwade, ²Shrikant V. Kamle, ³Rohan S. Bhojar ⁴Rohan S. Lokhande

¹Student, ²Proffeser, ³Student ⁴Student

¹Pharmacy,

¹Jagadambha Institute Of Pharmacy And Research , Kalamb 445401, INDIA

Abstract: Over the counter (OTC) medicines are the drugs that can be sold without the prescription of a registered medical practitioner to the consumer to treat infectious disease. The advantages of over- the-counter drugs are Lower cost, Convenience, Availability and the ability to control one's own disease When you use drugs inappropriately, the risk of drug abuse, addiction, and side effects increases. Abuse and misuse is characterized by taking too much of an approved treatment or prescription when the harms and negative consequences outweigh the benefits. These include self-medication with higher and longer doses than recommended. Knowledge and understanding need to be improved and legislation to promote the judicious and rational use of over-the-counter medicines needs to be introduced.

Index Terms - over-the-counter (OTC), drug abuse, drug addiction, misuse, self-medication,

1] INTRODUCTION

Over-the-counter (OTC) drugs are those that are sold directly without the need to present a prescription from a registered general practitioner. We often see a pharmacist rather than a doctor for minor ailments such as coughs and colds, headaches, backaches, toothaches, muscle pains, menstrual cramps, fever, etc.⁽¹⁾ these over-the-counter or over-the-counter medications are considered safe and effective and readily available. Available to the general public without a prescription. They are used primarily for symptom relief and not as a substitute for prescription drugs. ⁽²⁾ They play an increasingly important role in our self-care system and are the most widely used treatment for most common health problems. These over-the-counter medicines save time in medical centers, save high consultation fees and save time from long queues at the doctor's office. ⁽³⁾ The irrational use of these drugs has raised concerns among the medical fraternity about the safety of their self-medicating patients. These concerns quickly grew due to the incorrect knowledge of side effects such as antibiotic resistance, skin problems, hypersensitivity and allergies. ^(4, 5) young adults and adolescents buy and use over-the-counter drugs, and some of them may take these drugs without reading the directions for use. ⁽⁶⁾ Significant problems and malpractices were identified with over-the-counter drugs, such as sharing over-the-counter drugs, using expired drugs, doubling the dose of a drug when ineffective, storing over-the-counter drugs, and not reading labels and expiration dates.⁽⁷⁾

This article provide an overview of Over- The- Counter Drug their historical background, current Indian regulation, effect of drug on health, drug addiction, drug abuse, treatment for drug overdose, example of some OTC drug and their indication, advantages and disadvantages of the OTC drug etc.

2] HISTORICAL BACKGROUND

In the old days before the Food and Drug Administration (FDA), most drugs were available without a prescription, bottled and sold as medicine. Narcotic drugs and psychotropic substances such as alcohol, cocaine, marijuana, and opium have been included in some over-the-counter products without informing users. ⁽⁸⁾ The Food, Drug, and Cosmetic Act was drafted and implemented in 1938, which empowered the FDA to issue clear guidelines for which drugs could be sold by prescription only and which could be sold as

OTC. In 1951, an amendment to the FD&C Act went into effect to clarify the difference between over-the-counter and prescription drugs and to address drug safety issues. Prescription drugs were defined as compounds that could be addictive, toxic, or dangerous for use except under the supervision of a physician.

Anything

Else could be sold as OTC. In 1962, an additional amendment was made to the FD&C Act where drugs were expected to be effective and safe for administration as OTC. Regardless, viability and welfare decisions were problematic at the time. What is effective for one individual may not be effective for another, and any drug can cause unwanted side effects. ⁽⁹⁾

3] CURRENT INDIAN REGULATION FOR OTC DRUGS

Government and non-governmental public health organizations are increasingly drawing attention to the misuse, abuse and addiction of over-the-counter drugs in India. ⁽¹⁰⁾ Easy access with little or no quantity restriction to a wide range of over-the-counter drugs is a major factor responsible for irrational use leading to threatening health complications (antimicrobial resistance, increased mortality and morbidity) and economic damage. ⁽¹¹⁾ Failures in India's pharmaceutical regulatory environment, combined with poor community literacy regarding drug safety and use, potentiate the misuse and overuse of drugs leading to addiction. Insufficient guidance and knowledge of several drugs that are not classified in any category as to whether to dispense the drug as OTC or not. Unlike prescription, over-the-counter drugs are not defined as a separate category of drugs. However, few articles and reports indicate that the government is considering and is likely to identify and prepare a list of over-the-counter drugs in due course. ⁽¹²⁾ Developments come in certain recommendations made by the Drugs Consultative Committee (DCC). The DCC, during its 57th meeting held on 20 August, recommended that a suitable amendment be made in Annexure

K of the D&C Rules to incorporate the necessary provisions for over-the-counter drugs to provide exemptions from prescription and/or sales license requirements, with subject to suitable conditions. , 2019. He further recommended that the Ahuja Committee should determine the list of over-the-counter drugs along with conditions and make a proposal to amend the D&C rules. ⁽¹³⁾

3.1] INDIAN REGULATION

At present, there is no OTC schedule in the drug and cosmetics Rules 1945. Hence, any drug outside schedule H, G, and X is considered to be an OTC drug

3.1.1] SCHEDULE K

- a) Household remedies
- b) Item No.13
- c) Form 20 A
- d) Form 20 B

Examples

- i. Aspirin tablets, Antacid preparation, Analgesic balm etc.
- ii. Cold and nasal congestion preparation and syrups, lozenges, pills and tablets for cough
- iii. Digene (antacid)
- iv. Paracetamol

3.1.2] Exemption of schedules G, H or X

- a) Topical or external use (except ophthalmic and ear / nose preparation containing antibiotic and / steroids) application of the ingredients from these schedule.
- b) Clause -2: The salts, esters, derivatives and preparations containing the above substances excluding those intended for topical or external use.

Examples

- i. Diclofenac (volini Gel).
- ii. Clotrimazole.
- iii. Oxymetazoline.
- iv. Chericof and Honitus (Chlorpheniramine).

3.1.3] AYURVEDIC OTC DRUG

The Ayurvedic state Licensing Authorities.

Examples

- i. Vicks Vapor-rub
- ii. Amrutanjan Pain Balm,
- iii. Zandu Pain Balm,
- iv. Iodex Pain Balm,
- v. Moov Pain Cream
- vi. Itch Guard Cream,
- vii. Eno Fruit Salt Antacid

3.2] MARKETING AUTHORISATION

- ❖ The Drugs and Cosmetics Act, 1940 (DCA) and its subordinate legislation, the Drugs and Cosmetics Rules, 1945 (DCR)
- ❖ Other regulations are which have a bearing on the pharmaceutical business in India;
- ❖ In the 1995 Drug (Prices Control) Order, for instance, included acetylsalicylic acid and ephedrine.
- ❖ Drugs (Magic Remedies) Objectionable Advertisement Act, 1954

3.3] PATIENT INFORMATION

- ❖ Rule 96 of the DCR
- ❖ Rule 97
- ❖ Maximum Retail Price (MRP) Printed on the label. The (Packaging Commodities) Standards of Weights and Measures Act
- ❖ Warnings
- ❖ Symbols (Rx, X)
- ❖ Rule 161

3.4] DRUG REGISTRATION IN INDIA

- ❖ Non Prescription (OTC) Registration
- ❖ Single or combination containing non-prescription drugs, i.e. out of schedule G, H or X cannot be directly granted as OTC.
- ❖ Initially, it will be approved as a prescription (Rx), and subsequently, an application must be submitted to switch from Rx to OTC.

4] REASON FOR SELF MEDICATION

A country with a large population like India faces the challenge of an abysmally low doctor-to-patient ratio, which creates a favorable atmosphere for over-the-counter drug preference to flourish. Some specific reasons for the same may be mentioned below:

- 1) Have a previous prescription.
- 2) Saving time.
- 3) Advice from a family member.
- 4) The high price of a doctor's visit.
- 5) Overcrowded health centers.
- 6) Lack of trust in doctors.
- 7) Nurse's Council.
- 8) Pharmacist's recommendation.
- 9) Poverty, ignorance, unbelief.
- 10) Extensive advertising.
- 11) Availability of medicines elsewhere than in the pharmacy.
- 12) Other reasons.

4] CHOSSING AND USING OVER- THE- COUNTER DRUGS

Errors are more likely to occur when consumers self-diagnose and often write their own prescriptions. In rare instances, for instance, a straightforward headache may serve as an early indicator of a brain tumor or hemorrhage. Although the majority of headaches are not harmful, this incorrect diagnosis can lead to serious complications. Similarly, a severe heartburn may signal an impending heart attack. Ultimately people must be more cautious when determining if their symptom or requires medical attention by a physician or pharmacist.

The following are guidelines for selecting over-the-counter medications:

- ❖ When self-diagnosing, make sure it is as precise as possible and not predicated on conjecture to prevent additional health issues.
- ❖ Choose goods free of allergens and with a minimal number of suitable ingredients. Increased risk and treatment costs result from the use of needless medications made with more active ingredients.
- ❖ Read label carefully to determine the correct doses, their side effects and contraindications
- ❖ Consult a pharmacist or physician about the medication, whenever in doubt.
- ❖ Check for possible drug-drug interactions with other drugs in case of polypharmacy
- ❖ Adhere strictly to the prescribed dosage, and seek advice from a pharmacist or physician if symptoms persist.
- ❖ Never take over-the-counter medications for longer than is advised. If the condition does not improve, see a doctor or pharmacist right away.

6] EXAMPLES OF SOME OTC DRUGS AND THEIR INDICATION:

1) Systemically acting drugs:

DRUGS	INDICATIONS
Bromphniramine	Antihistamine.
Chlophendianol HCl	Antitussive.
Cimetidine	Gastric acid reducer
Clemastine fumarate	Antihistamine.
Diflunisal	Analgesic
Dyclonine HCl	Oral local anesthetic, analgesic
Famotidine	Gastric ulcer reducer.
Lopramide	Antidiarrheal.
Methocarbimol	Muscle relaxant.

2) Topically acting drugs:

DRUGS	INDICATIONS
Ketoconazole	Dandruff.
Minoxidil	Hair grower
Oxymetazoline HCl	Nasal decongestant.
Xylometazoline HCl	Nasal decongestant

7]EFFECT OF OVER-THE-COUNTER DRUGS ON HEALTH

Clinically speaking, it is not desirable to use medications inappropriately because it exposes the user to risk without their knowledge. Benefits cannot be guaranteed, and there is a chance of various negative effects. Concerns regarding commonly seen OTC medication resistance are increasing rapidly. Since there is little evidence of OTC abuse or misuse in India. ⁽¹⁴⁾

In small doses, OTC epinephrine is thought to be safe and effective, but when misused or abused, it can have serious negative effects. Death can be a leading possible outcomes. In Finland, few community pharmacies observed that vitamins and natural medication comprised 9% of drug-related problems, among which lactic acid bacteria preparations were commonly mentioned product category. ⁽¹⁵⁾ As a widely used cough suppressant, dextromethorphan [DXM] has replaced codeine due to its greater availability, higher efficacy, and low toxicity profile at recommended dosages. Due to its accessibility as over-the-counter cough syrup, DXM is easily abused and can cause psychosis (delusions, hallucinations, and paranoia) when taken in excess (1500 mg/day). ⁽¹⁶⁾ Like other opioids, loperamide can cause euphoria. It is sometimes used to temporarily reduce cravings and withdrawal symptoms. When loperamide is misused, it can result in loss of consciousness, nausea, constipation, ocular abnormalities, and dizziness. It can induce irregular or rapid heartbeats, as well as kidney disorders. OTC painkillers such as Ibuprofen and codeine have been linked to the deaths of two consumers, ages 49 and 41, who suffered from respiratory depression and renal failure, respectively. Addiction, according to recent coroner's inquests. Few over-the-counter medications are taken off the market for safety concerns, such as co-proxamol, an analgesic combination that contains paracetamol and the opioid dextropropoxyphene. Even at low dosages, acetylsalicylic acid may negatively impact thrombocyte activity, according to reports. Treatment for acetylsalicylic acid poisoning is especially important when using extraction techniques like cold water, which helps get rid of

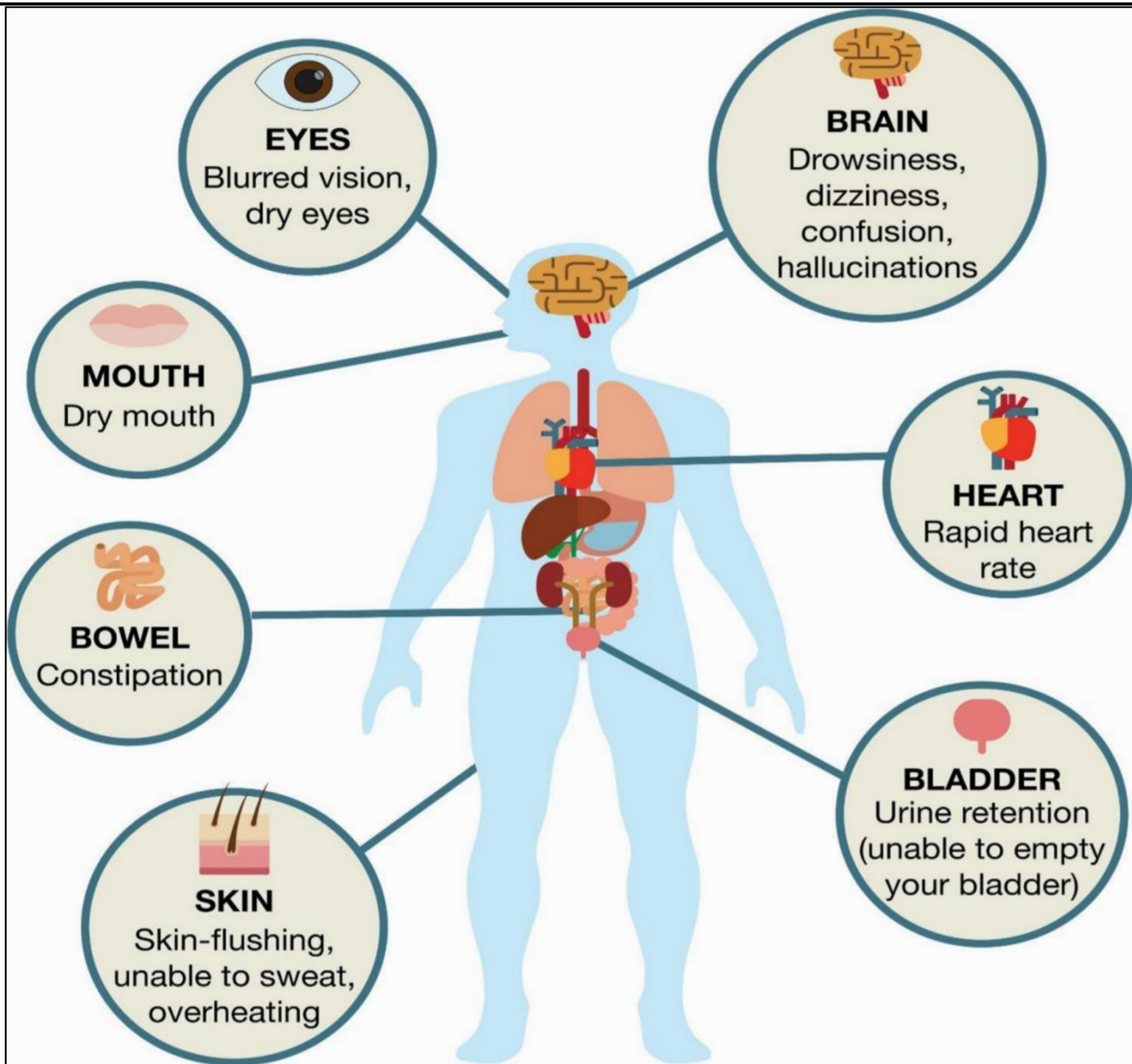


Figure 1: Effect of Over-The-Counter drug on health

8] REASONS FOR OTC DRUG SIDE EFFECTS

- Ineffective treatment of the illness and its symptoms may result in the overuse of medications and their negative side effects.
- Adverse effects can arise from the misuse or overuse of medications that are effective.
- A patient who receives an incorrect diagnosis and takes the wrong OTC medication may present with a potentially serious but treatable disease.
- Unfavorable risk-benefit ratio.
- High potential for misuse and abuse.
- A consumer's lack of awareness, as they are unable to assess the drug's safety effects.
- Inadequate labeling of OTC products.
- Low socio-economic strata.
- Use of multiple medications – polypharmacy.

9] OTC DRUGS-ADDICTION, ABUSE, TREATMENT

9.1] OTC drugs-addiction

According to data from the Substance Abuse and Mental Health Services Administration [SAMHSA] in the US, approximately 3.1 million persons aged 12 and older have misused OTC drugs at least once in their lives. OTC drug abuse has increased, particularly in young adults and teenagers. OTC medications are often used by patients to self-medicate at home. The misuse of drugs can lead to serious physical health problems, dependence, and addiction when abusing over-the-counter medications, some may switch to marijuana or other prescription medications for a potent high.

While not all over-the-counter medications have the potential to lead to addiction, some do. The misuse of Dextromethorphan and Loperamide can lead to addiction according to National Institute on Drug Abuse. Over-the-Counter (OTC) drug addiction can arise from long-term, chronic abuse and lead to serious health issues, work-related issues, or educational difficulties. There is a significant risk of accidental overdose, which can be fatal and result in long-term harm to the body and brain. OTC drugs carry risks when misused, whether mildly or severely with many drugs, the body craves more the more you use them, which leads to increased tolerance and addiction.

- The signs of an OTC drug addiction are as follows:
- Using more of the drug than recommended.
- Lying about how much usage.
- Hiding medicines from others.
- Medicine stealing.
- Prolonged medication use, regardless of adverse effects
- Purchasing medication in bulk due to concern that it might run out.^(17,18)

When we stop taking OTC drugs, they may even cause withdrawal symptoms if they become addictive. Depending on the kind of medication, how long it has been used for, and the dosage, the symptoms can be classified as mild, moderate, or severe. Typical withdrawal symptoms include:

- Nausea
- Agitation
- Confusion
- Mood changes
- Craving
- Anxiety

Treatment for OTC drug addiction:

If addicted to certain over-the-counter drugs, cognitive behavioral therapy and other forms of therapy have been successful in helping people from addiction, and detox is the first step of treatment. ^(17, 19)

OTC drug Detox: In order to avoid severe withdrawal symptoms and medical emergencies, this program offers medical management of withdrawal symptoms. Additionally, this program offers clinical assistance to help overcome the psychological effects of stopping OTC drug.

OTC drug rehab: Rehab program also help provide structural and ongoing support to kick substance abuse habits for good. They also provide behavioral therapy and support to make positive life changes to overcome addictive behaviors.

The most common approaches of OTC addiction treatment are:

- Educational seminars
- Behavioral therapy
- Recovery support group
- Life skills development

9.2] commonly abused OTC drugs

The sale of over-the-counter (OTC) medicines from pharmacies can help individual's self-manage symptoms. However, some OTC medicines may be abused, with addiction and harms being increasingly recognized are as follows:

- Cough suppressants (Dextromethorphan)
- Pain relievers (Acetaminophen and Ibuprofen)
- Nasal decongestants (Pseudoephedrine)
- Antihistamine/Motion sickness (Dimenhydrinate and diphenhydramine)
- Caffeine
- Laxatives
- Diet pills (Ephedra)
- GI ailments like hyperacidity/constipation/diarrhea/ nausea (Digene, Zinetac, Uri enzyme, Lomotil, Dulcolax).
- Skin conditions such as burns, rashes, acne, and cuts (Aiol, Caladryl, Flutivate, and Betadine Candid).
- nutritional supplements (Ferrodal, Shelcal, Becosules, Coba Dex, and Protinex). ^(17,19)



9.3] Treatment for OTC overdose

Taking too many OTC medicines can lead to liver damage, stomach bleeding, and kidney diseases. For taking an OTC medication first, it's important to know what kind of pain reliever you're taking. OTC pain relievers are available as two major classes – Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and acetaminophen.⁽²⁰⁾ Nearly one in four patients show they exceed the recommended dose of acetaminophen on one or more common OTC products, and 5 % dosed out amounts that could cause serious harm (> 6 grams). Furthermore, almost 50% of patients overdose by taking two over-the-counter medications that contain acetaminophen at the same time .In OTC drug overdoses, acetaminophen and NSAIDs have been the most common.⁽²¹⁾ The use of over-the-counter (OTC) products appears to be rising as more people switch from prescription medications to OTC drugs. Older adults are the largest consumers of OTC medications, taking on average 4 OTC medications per day which may also lead to heart failure in some cases.⁽²²⁾

- **Avoid double dosing:** OTC pain killers and fever reducing agents are safe and effective when taken as per the instructions. Always ensured not to consume medications with similar active ingredients. In such a situation, a double dose will be required. It's crucial to speak with a doctor about any previous health issues, current medications, and any supplements being taken.

- **Read drug labels:** Drug labels include the list of active and inactive ingredients present and provide instructions on their usage if you have any questions about medications, speak with a physician or a pharmacist.

- **Overdose:** Signs and symptoms may not be seen initially but may cause nausea or vomiting, heartburn, abdominal pain, constipation, dizziness, fatigue, bleeding or bruising, jaundice, confusion, fever.

All labels should be read properly and taken only as directed, over-dosing or using them for a longer time than indicated should be strictly avoided. If you're unsure how to use an over-the-counter medication, speak with a doctor or a pharmacist.

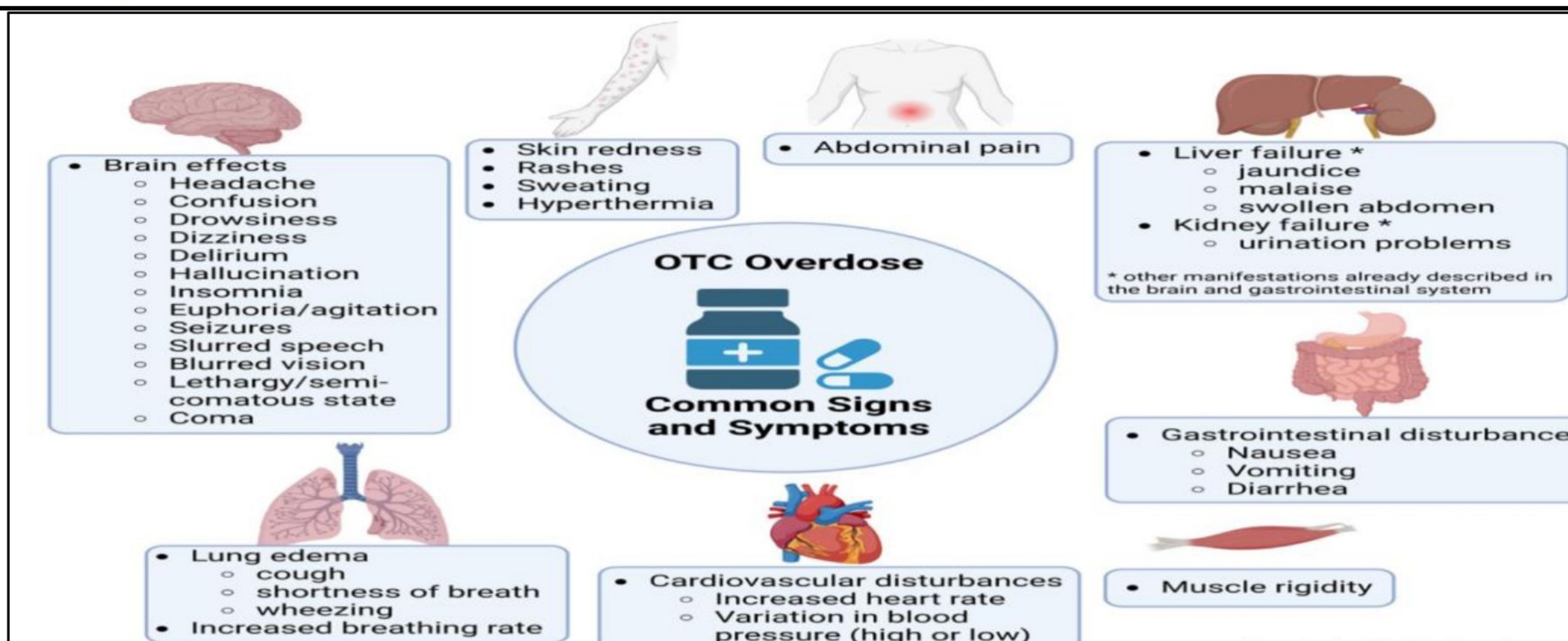


Figure 2: common sign and symptoms of OTC drug overdose

10] APPROACHES TO OVERCOME THE OTC DRUG MISUSE AND ADDICTION

The growing issues and gaps surrounding self-medication, including drug abuse, overdosing, incorrect diagnosis, drug interactions, polypharmacy, etc., can be filled by implementing some of the (internationally employed) techniques covered below.

10.1] Proper labelling of OTC medications

The biggest problem is the lack of complete information on OTC drug labels, which can cause a number of problems including side effects and drug interactions. The FDA established a law in 2008 mandating that over-the-counter medications bear a new label known as "Drug Facts." It should contain details about the active ingredients, uses, precautions, and usage instructions. And inactive ingredients this helps prevent any negative effects and guarantees that the patient uses the over-the-counter medication as directed. Figure 3. Depicts the Drug Facts label for the over-the-counter drug Acetaminophen includes information about ingredients, uses, warnings and directions. The therapeutic category and the required dosage are not even included in the mandatory information on OTC pharmaceutical labels in India, which is frequently insufficient for the patient to make an informed decision about self-medication. ⁽²³⁾ Thus, the approach of a new label called "Drug Facts" can be reciprocated in India for adequate and complete information on the label OTC medicine. Given the variety of languages spoken in India outside English, it will be beneficial to provide OTC medication labels in the local tongues. Additionally, tamper-proof packaging can be implemented to make it simple to detect any tampering with the label of over-the-counter drug packages. Lastly, patients, particularly those with lower levels of education, may find it useful if the label includes a picture explanation.

10.2] Raising awareness

The general public started self-medication during COVID-19 as a precaution against contracting the virus. In this case, it is imperative to educate the public about the dangers of excessive drug use. ⁽²⁴⁾ In addition, pharmacist, and consumer awareness camps regarding the need for OTC or prescription medicine, side effects, dosage specification, and avoidance of polypharmacy may further streamline OTC management.

10.2.1] Customer self-management awareness

Giving consumers the tools they need to make wiser, more responsible decisions is one of the main tenets of a robust over-the-counter (OTC) ecosystem. Information technology and mobile application-based healthcare programs are a recent development in the healthcare sector, given the sharp increase in mobile phone users in India. One well-known instance of such a service is MHealth. MHealth is typically classified as having access to health-related queries and information using mobile phones and delivery of healthcare services. ⁽²⁵⁾ A MHealth-based application (Epocrates / Epocrates Plus) is commonly used in the United States for drug-related information, safety profiles, generics, OTC medicines, and doses. ⁽²⁶⁾ Similarly, Indonesian consumers use MHealth to search for trusted medical information, find the best hospitals, and deliver OTC medicine to their own houses. ⁽²⁷⁾ In India, such applications are more prevalent in urban areas instead in rural extents. This is ascribed to issues like low knowledge of smartphones, frequent blackouts, low literacy rates, and resistance to progress. It will take a community-based approach to raise awareness among the rural populace. An effective consumer health ecosystem with innovative tactics, awareness campaigns, and over-the-counter access has the potential to drastically change India's healthcare situation. This kind of approach also helps to

improve patient care for urban consumers and improve healthcare access for the large impoverished rural population. In the current situation, consumers who are armed with innovative products and a deeper comprehension of healthcare solutions could produce a more tranquil and improved healthcare system.

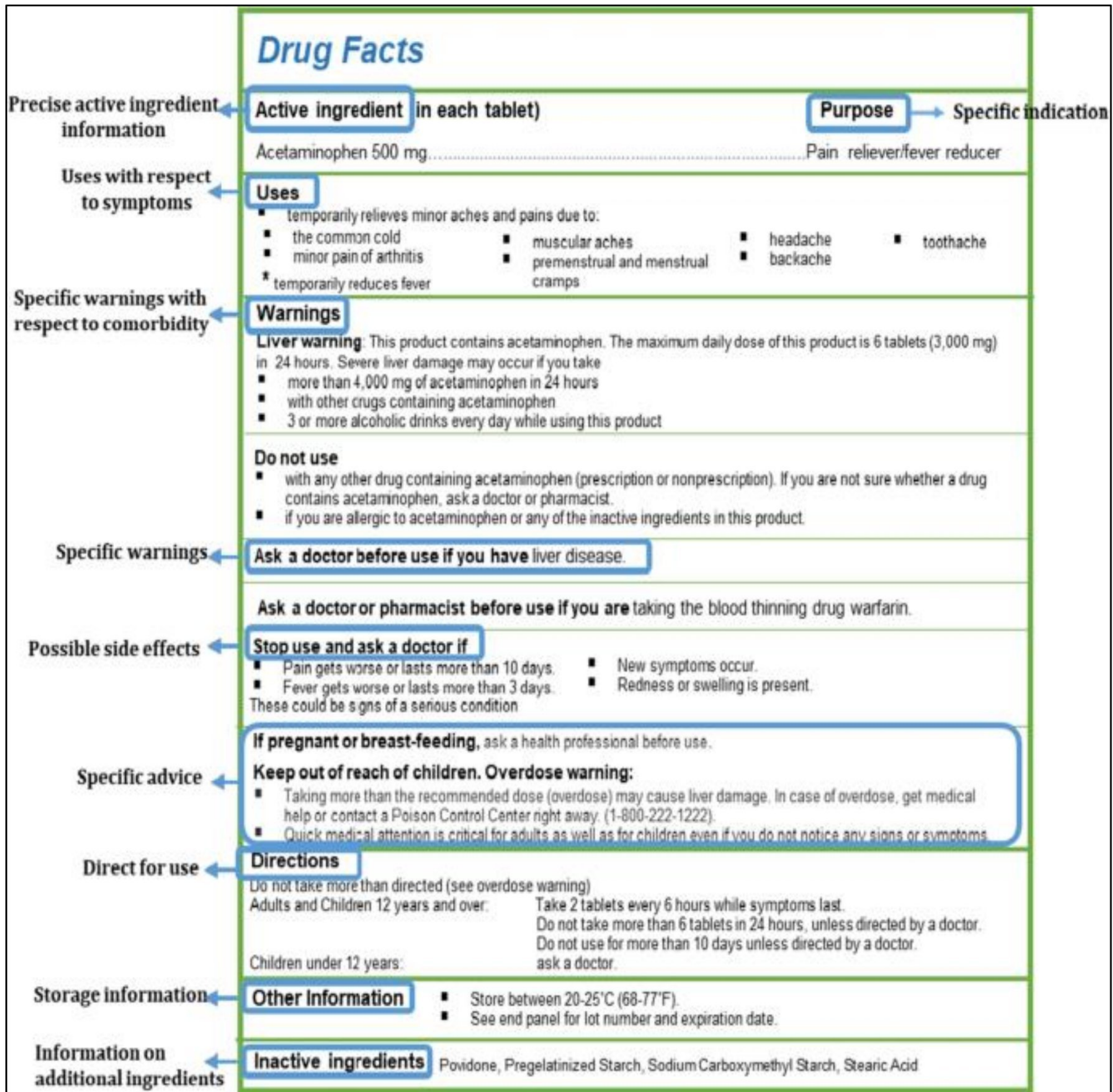


Figure3: The Drug Facts label for the over-the-counter drug Acetaminophen includes information about ingredients, uses, warnings, and directions

10.2.2] Extended role of pharmacist in OTC medication

Particularly in remote areas without easy access to doctors, pharmacists are vital to the delivery of healthcare services. Where primary care physician services are prohibitively expensive, the community pharmacy serves as the only lifeline of the healthcare system. Moreover, Rx-to-OTC switches generate more possibilities for a pharmacist to serve the community by offering primary health care services to consumers. The role of pharmacists in monitoring the potentially inappropriate use of over-the-counter (OTC) medicines has grown in light of their increased accessibility. In addition to monitoring or recommending a safe and suitable option based on the needs of the customer, the pharmacist may also offer advice regarding non-pharmacological approaches, where medication seems to be avoidable. Furthermore, a pharmacist's recommendation of a generic equivalent based on the needs of the customer is crucial in promoting affordability. Babar (2021) has therefore offered a number of suggestions that can support pharmacy practice in low- and middle-income countries (LMICs) in order to strengthen pharmacy practices. (28)

These recommendations are:

- Community pharmacies are required to have graduate-level pharmacists on staff.
- Clearly defining the responsibilities and roles of graduate and diploma pharmacists
- Effective classification and distribution of medications into three categories: a) prescription drugs, b) drugs available only through pharmacists, and c) over-the-counter drugs
- Implementations of stringent regulation controlling the sale of medicines • Forbidding doctors from dispensing medicines
- Putting in place universal health coverage programs that work with pharmacists and pharmacies to make medications more affordable.
- Strengthen the role of national medicines regulatory authorities
- Provide pharmacists with the necessary clinical education and minor illness plan implementing the national medicines information strategy to provide accurate medication information to patients and medical professionals
- Programs for pharmacists' mandatory continuing professional development (CPD).

11] ADVANTAGES

1. It provides a trading platform for smaller and less liquid companies as they are not qualified to be listed on a standard stock exchange
2. It is a cost effective method for corporations as there is lower cost of new issues and lower cost of serving investors.
3. Family concerns and close companies can enter the stock market through OTC.
4. Dealers may, as they choose, operate both on new issues and on the secondary market.
5. It gives more freedom of choice to the investors to select shares by market making dealers in both primary and secondary markets.
6. It is a transparent trading system with no problems with bad or short deliveries.
7. Information flows free and more direct from market makers to customers because there is close contact between them.
8. OTC trading is a common practice in the energy market and represents the largest volume of trades in the electricity market in many countries.
9. The OTC market is different from a regular stock exchange because it is decentralized and does not take place in one place OTC transactions happen directly and electronically between two parties.

12] DISADVANTAGES

1. Limitation of opportunities to receive advice on possible lifestyle therapies (e.g. exercise and diet).
2. Poorer compliance with regulations,
3. Wrong diagnosis, patients will not benefit from the drug but will be exposed to its risks,
4. It is more difficult to study the effects of the drug.
5. Increased likelihood of stroke or heart attack.
6. Gastrointestinal problems.
7. Liver and kidney damage
8. Dehydration.
9. Hallucinations and delusions.
10. Depression and anxiety

13] CONCLUSION

Self-medication and self-care are essential elements of any health care system. The self-medication process involves the use of over-the counter (OTC) medications. Pain, coughs and colds, constipation, acne, and other common ailments and symptoms are treated with over-the counter medications. Some over-the-counter medications contain active ingredients that could be abused if used in higher than recommended doses. Codeine-based drugs (primarily compound analgesics), cough suppressants (especially dextromethorphan), sedatives, decongestants, and laxatives identified as five major classes for self-medication. The popularity of over-the-counter drugs among patients can increase their potential for abuse. Physiological or psychological harm (e.g., narcotic addiction), harm caused by another chemical (e.g., NSAID-related gastric bleeding), and social and economic concerns were among the associated harms. Pharmacist vigilance and patient counseling

can help reduce over-the-counter drug abuse. Limiting supply, raising awareness among the public and professionals, and using existing supports and services are among the strategies and actions used, while related studies are insufficient. Further research should be conducted to quantify the extent of abuse, assess management and record individual experiences to inform policy, legislation and interventions.

14] REFERENCES

1. Dickinson BD, Altman RD, Deitchman SD, Champion HC. Safety of over-the-counter inhalers for asthma: Report of the council on scientific affairs. *Chest*. 2000;118(2):522-6. doi: 10.1378/chest.118.2.522, PMID 10936150.
2. Ferner RE, Beard K. Over the counter medicines: Proceed with caution. *BMJ*. 2008;336(7646):694-6. doi: 10.1136/bmj.39504.389676.AD, PMID 18369225.
3. Foley M, Breindahl T, Hindersson P, Deluca P, Kimergård A. Misuse of 'over-the-counter' codeine analgesics: Does formulation play a role? *Public Health*. 2016;130:95-6. doi: 10.1016/j.puhe.2015.10.006, PMID 26612458.
4. Bennadi D. Self-medication: A current challenge. *J Basic Clin Pharm*. 2013;5(1):19-23. doi: 10.4103/0976-0105.128253, PMID 24808684.
5. Marathe PA, Kamat SK, Tripathi RK, Raut SB, Khatri NP. Over-the-counter medicines: Global perspective and Indian scenario. *J Postgrad Med*. 2020;66(1):28-34. doi: 10.4103/jpgm.JPGM_381_19, PMID 31898596.
6. Barrenberg E, Garbe E. Use of over-the-counter (OTC) drugs and perceptions of OTC drug safety among German adults. *Eur J Clin Pharmacol*. 2015;71(11):1389-96. doi: 10.1007/s00228-015-1929-5, PMID 26300207.
7. Bekele KM, Abay AM, Mengistu KA, Atsbeha BW, Demeke CA, Belay WS, et al. Knowledge, attitude, and practice on over-the-counter drugs among pharmacy and medical students: A facility-based cross-sectional study. *Integr Pharm Res Pract*. 2020;9:135-46. doi: 10.2147/IPRP.S266786, PMID 32983946
8. Nabors LA, Lehmkuhl HD, Parkins IS, Drury AM. Reading about over-the-counter medications. *Issues Compr Pediatr Nurs*. 2004;27(4):297-305. doi: 10.1080/01460860490884192, PMID 15764435
9. Lynch SS. Overview of over-the-counter drugs. *MSD Manual [internet]*; 2019. Health Care. Available from: <https://www.msdmanuals.com/en-in/home/drugs/over-the-counter-drugs/overview-of-over-the-counter-drugs> [cited 21/3/2022]
10. Porter G, Grills N. Medication misuse in India: A major public health issue in India. *J Public Health*. 2016;38(2):e150-7. doi: 10.1093/pubmed/fdv072.
11. Balamurugan E, Ganesh K. Prevalence and pattern of self-medication use in coastal regions of South India. *Br J Med Pract*. 2011;4(3).
12. Raghavan P. India may soon give OTC drugs definition; 2017 Sep 20. *The Economic Times [internet]*. Available from: <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-may-soon-give-otcdrugs-definition/articleshow/60757040.cms> [cited 21/3/2022]
13. Sapra A, Lenin B, Jain K. Over the counter drugs – regulatory clarity on the horizon. *India corporate law*. Vol. 30; 2019.
14. Hampton LM, Nguyen DB, Edwards JR, Budnitz DS. Cough and cold medication adverse events after market withdrawal and labeling revision. *Pediatrics*. 2013;132(6):1047-54. doi: 10.1542/peds.2013-2236, PMID 24218462.
15. Ylä-Rautio H, Siissalo S, Leikola S. Drug-related problems and pharmacy interventions in non-prescription medication, with a focus on high-risk over-the-counter medications. *Int J Clin Pharm*. 2020;42(2):786-95. doi: 10.1007/s11096-020-00984-8, PMID 32078108.
16. Martinak B, Bolis RA, Black JR, Fargason RE, Birur B. Dextromethorphan in cough syrup: The poor man's psychosis. *Psychopharmacol Bull*. 2017;47(4):59-63. PMID 28936010.
17. Abuse and misuse potential of dimenhydrinate: A review of the clinical evidence [internet]. Ottawa, (ON): Canadian Agency for Drugs and Technologies in Health. (Rapid CADTH. Response reports); 2015. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK349880/> [cited 21/3/2022].
18. Presley B, Bianchi B, Coleman J, Diamond F, McNally G. Efficiency of extraction and conversion of pseudoephedrine to methamphetamine from tamper-resistant and non-tamper-resistant formulations. *J Pharm Biomed Anal*. 2018;156:16-22. doi: 10.1016/j.jpba.2018.04.016, PMID 29684907.
19. Graddy R, Buresh ME, Rastegar DA. New and emerging illicit psychoactive substances. *Med Clin North Am*. 2018;102(4):697-714. doi: 10.1016/j.mcna.2018.02.010, PMID 29933824.

20. Wolf MS, King J, Jacobson K, Di Francesco L, Bailey SC, Mullen R, et al. Risk of unintentional overdose with non-prescription acetaminophen products. *J Gen Intern Med.* 2012;27(12):1587-93. doi: 10.1007/s11606-012-2096-3, PMID 22638604.
21. Szkolnicka B. Prescription and over-the-counter medication in deliberate self-poisoning and accidental overdosing--preliminary study. *Przegl Lek.* 2005;62(6):568-71. PMID 16225126.
22. Page RL, O'Bryant CL, Cheng D, Dow TJ, Ky B, Stein CM, et al. American Heart Association Clinical Pharmacology and Heart Failure and Transplantation Committees of the Council on Clinical Cardiology; Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovascular and Stroke Nursing; and Council on Quality of Care and Outcomes Research. Drugs that may cause or exacerbate heart failure: A scientific statement from the American Heart Association. *Circulation.* 2016;134(6):e32-69. doi: 10.1161/CIR.0000000000000426, PMID 27400984.
23. Shankar R, Joshi M, Pathak K. Labeling of OTC drugs in India: Dilemma whether pharmacy centred or patient centred. *Indian J Pharm Practice.* 2016;9(3):199.
24. Malik M, Tahir MJ, Jabbar R, Ahmed A, Hussain R. Self-medication during Covid-19 pandemic: challenges and opportunities. *Drugs Ther Perspect.* 2020;36(12):565-7.
25. Lunde S. The mHealth Case in India: Wipro Council for Industry Research; 2013. [Available from: <https://smartnet.niua.org/sites/default/files/resources/the-mHealth-case-in-India.pdf>. Accessed 23 May 2022.
26. International Pharmaceutical Federation. MHealth—Use of mobile health tools in pharmacy practice: The Hague, International Pharmaceutical Federation; 2019. [Available from: <https://www.fp.org/files/content/publications/2019/mHealth-Use-of-mobile-health-tools-in-pharmacy-practice.pdf>. Accessed 18 May 2022
27. Octavius GS, Antonio F. Antecedents of intention to adopt mobile health (mHealth) application and its impact on intention to recommend: an evidence from Indonesian customers. *Int J Telemed Appl.* 2021;2021:6698627.
28. Babar ZU. Ten recommendations to improve pharmacy practice in low and middle-income countries (LMICs). *J Pharm Policy Pract.* 2021;14(1):6.

