Over the Counter Medications- An Account

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Abstract

Self-care with over-the-counter (OTC) medicines have evolved from the “dark ages” of patent medicine manufacture and sale to a modern era of new drug development involving prescription-to-OTC switch. This evolution is largely due to the OTC review, which placed science at the cornerstone of safety, effectiveness, and labelling of non-prescription medicines. As self-care with OTC drugs has evolved, the switching of drugs from prescription to non-prescription status has produced important benefits, creating more self-reliant consumers through novel self-care therapeutics, significant cost savings to the health care system, expanded markets for companies, enhanced science for regulatory decisions, a more consumer friendly label for all OTC agents, and a more consistent and predictable drug approval process. OTC drugs also known as Non-Prescription drugs are those medications which can be obtained without a Registered Medical Practitioner (RMP) and can be easily purchased in pharmacies, grocery stores, and convenience stores. According to American College of Preventive Medicine, they define OTC as “Drugs (Prescription and OTC drugs) are substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease”. The present study has been designed to investigate the benefits & risks, various classes and status of OTC medications in India.

Keywords: Fetus; non-prescription drugs; Over-the-counter medications; Pregnancy.

Introduction

OTC drugs are defined as safe and effective for use by the general public without a doctor’s prescription” [1] Their significant action and easy availability makes OTC to be the most purchased drugs in countries like India, United States of America, United Kingdom and other several parts of the world. There are over 80 therapeutic categories of OTC drugs which can be grouped in 12 broad therapeutic classes [1, 2]

Broad therapeutic classes of OTC medications

- Analgesics and antipyretics
- Cold, cough and allergy products
- Gastrointestinal products
- Dermatological products
- Other topical products (including dermal and vaginal, antifungal, anorectal medications, head lice, hair loss and Otic products)
- Ophthalmic products
- Oral health care products
- Menstrual products
- Nicotine replacement products
- Weight loss aids
The benefits of over the counter availability
1. Direct, rapid access to effective medicines.
2. Wide availability.
3. Decreased healthcare system utilization (fewer physician visits, lower healthcare system costs).
4. Allowing individuals to be in charge of their own health [3, 4].

Risks associated with OTC
1. Incorrect self-diagnosis delaying diagnosis and treatment of serious illnesses (delay in seeking advice from a healthcare professional)
2. Increased risk of drug-drug interactions
3. Increased risk of adverse events when not used appropriately
4. Potential for misuse and abuse. [3,4]

Statistics on OTC Use
“Accessibility, affordability, trust and empowerment” these four attributes epitomize the value of OTC medicines. Following statistics have full extent of OTC medicines [5]

A. OTC medications are accessible
1. OTC medications provide ACCESS 24/7 to conveniently available healthcare options to busy families and caregivers.
2. The availability of OTC medicines- off the shelf, without a prescription- provides symptomatic relief for an estimated 60 million people who otherwise would not have treatment.
3. While there are approximately 54,000 pharmacies in the United States, there are more than 750,000 retail outlets that sell OTC products. [5]

B. OTC medications are affordable
1. OTC medications provide affordable treatment options for both consumers and the US Healthcare system.
2. The availability of OTC medicines creates significant value for the US healthcare system around $102 billion in annual savings.
3. Consumers and taxpayers save $5.2 billion annually if half of the unnecessary visits to primary care physicians were avoided by more self-care, including greater use of OTC medications. [5]

C. OTC medications empower consumers
1. OTC medications empower individuals and families to meet their everyday healthcare needs
2. 96% of us adults believe OTC medicines make it easy for individuals to care for minor medical ailments
3. 70-90% of all illness episodes are addressed with self-treatment. [5]

D. Consumers trust OTC medicines
1. OTC medicines are a trusted first-line of defence for healthcare providers and consumers alike.
2. Consumers depend on OTC cough medicines as a first-response to relieve cough symptoms for themselves and their children
3. For a range of illnesses, 8 in 10 consumers use OTC medicines to relieve their symptoms without having to see a healthcare professional. [5]

OTC users’ categories
There are 4 vulnerable groups of OTC users as people under these groups are very susceptible towards the side effects as well as the adverse effects of OTC. These are
- Pediatric patients/Children.
- Women who are trying to get pregnant/ are pregnant or are breastfeeding.
- Geriatric patients.
- Special groups: people having health problems and people taking prescription drugs (epilepsy, glaucoma, gout, heart disease, high blood pressure, stroke, thyroid problems, diabetes, bleeding disorders etc.) [6].

A. Medications for children
Drugs are processed differently in children from an adult, so it is not wise to guess the dose based on the child’s size (Table 1 & 2).
1. Do not give OTC drugs to babies and children under 2 years old without consulting the doctor.
2. Never give your child medicines such as aspirin- they can often lead to fatal condition that affects the brain.
3. Pay close attention to the label and composition of the preparation.
4. While giving liquid medications, use precise measuring spoons or droppers marked for the correct dose, not kitchen spoons.
5. Keep all drugs, both prescription and OTC, out of the reach of children at all times. [6]

In order to provide safe and effective drug therapy to such category of patients, it is important to gain knowledge of the pharmacokinetic and pharmacodynamic properties of each drug and the effect of development on its decomposition. The chronological details of pediatric patients has been shown in table below [7]

The most commonly used OTC medication in children are the analgesics/antipyretics, acetaminophen and ibuprofen.

<table>
<thead>
<tr>
<th>Table 1: Chronological details of pediatric patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.no</td>
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<td>5</td>
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</table>

<table>
<thead>
<tr>
<th>Table 2: Effects as well as side effects of OTC used in children</th>
</tr>
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<tbody>
<tr>
<td>S. No</td>
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</table>
B. Medications for pregnant and breastfeeding

Drugs, including OTC cold medications and pain relievers, can pass from a mother to her unborn baby (Table 3) which is the reason that most of the pregnant women undergo the state of dilemma to either use go for a prescription drug or for a non-prescription drugs. Most of the drugs taken by the pregnant women can cross the placenta and exert their pharmacological and teratogenic effects on the developing embryo/fetus [6, 7].

Table 3: OTC medications may be used during pregnancy

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Drug class</th>
<th>Cross placenta?</th>
<th>Use in pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Non-narcotic analgesic/antipyretic</td>
<td>Yes</td>
<td>Pain reliever of choice</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Salicylate analgesic/antipyretic</td>
<td>Yes</td>
<td>Not recommended except for specific indications*</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>NSAID analgesics</td>
<td>Yes</td>
<td>Use with caution; avoid in third trimester</td>
</tr>
<tr>
<td>Ketoprofen</td>
<td>NSAID ANALGESIC</td>
<td>Yes</td>
<td>Use with caution; avoid in third trimester</td>
</tr>
</tbody>
</table>

*associated with increased perinatal mortality, neonatal hemorrhage, decreased birth weight, prolonged gestation and labor, and possible teratogenicity [8, 9].

Safety measures

1. Studies reveal that aspirin can increase risk of gastroschisis in a number of pregnant women.
2. Ibuprofen and other nonsteroidal anti-inflammatory drugs like acetaminophen have been linked to the premature closure of the fetal ducts when used in third trimester.
3. Pseudoephedrine can cause high risk of having a baby born with gastroschisis if taken first trimester
4. Pregnant women should consult a doctor while taking an OTC medicine.
5. Precautions while prescribing an OTC drug to a pregnant woman
   a) Treat minor ailments without drugs.
   b) The prescribed drug should be that one which is considered as safe during pregnancy.
   c) Drugs which have been used for a longer duration of time should be prescribed as compared to the newly introduced drug into the market.
   d) Adjust the dose of the drug depending upon the pregnancy stage [8-11].

C. OTC medication for a breast feeding mothers

Most medications are transferred into breast milk if they attain high concentrations in maternal plasma, have a low molecular weight, and are low in protein binding and are lipid solid resulting in the low quality of milk [12, 13].

Safety measures

1. Drugs having half-lives, high protein binding, low oral bioavailability or high molecular weight should be considered first
2. One should not prescribe drug that is newly introduced into the market
3. One should avoid long-acting formulations.
4. Keep in check about the side effects of that particular OTC which a breast –feeding woman is taking [14].

D. OTC medications for geriatric

Adults of 60 years age group generally have more medical problems and use more medications, both prescription and OTC, when compared to younger adults [15]. Because older adults often experience chronic health conditions that require treatment with multiple medications, there is a greater likelihood of experiencing unwanted drug side effects [16] (Table 4).

Safety measures

1. Do inform your doctor as well as pharmacist about your intake of any drug (vitamins, antibiotics, prescription as well as OTC drug)
2. Tell your doctor weather you are allergic to that particular drug
3. Do notify your doctor about the side effects caused by any drug
4. Always follow your doctor’s advice, read the guidelines given on the leaflet and make sure that you take your medicines regularly at fixed intervals.
5. Ask your queries related to that particular drug to your doctor or pharmacist. [17]
Reasons for the growth of OTC market

1. Purchasing power parity
2. Wider destruction channels
3. Direct to customer advertisements
4. Low price controls [18]

OTC retail sales totaled $17 billion (excluding Wal-Mart sales) in 2010. [19] Currently, 35% of adult Americans use OTC medications on a regular basis and there is a trend for increasing use of more drugs move from prescription to OTC status. [1] The Centre for Drug Evaluation and Research (CDER) division of the Food and Drug Administration (FDA) OTC medications to ensure that they are properly labeled, their benefits outweigh their risks, their potential for misuse and abuse is low, and their health practitioners are not needed for their safe and effective use. [1]

OTC medications value and sales

The worldwide market for over-the-counter drugs could exceed $70 billion by 2015

1. US. Consumers make 26 trips a year to purchase OTC product. For every dollar spent on OTC medicine, the us healthcare system saves 6-7 dollar [20]

2. Patients buy OTC as they are cheap and affordable
3. 8 in 10 individuals give their first preference to an OTC drug without seeking help of a registered medical practitioner
4. A study of seven European countries found that increase in self-medication could save more than €11.5 billion annually[21]
5. OTC medications helps to reduce healthcare costs by offering safe, effective medicines to over 180 million people for commonly occurring conditions.[12]
6. 9 out of 10 individuals in Europe view self-care as a vital part of the management and prevention of both minor ailments & prevention of both minor ailments and chronic conditions and diseases. OTC medicines help in fulfilling the growing consumer appetite for self-care[13]
7. Research shows that 81% of the adults use OTC medication as a treatment of minor ailments[22]
8. If OTC medicines were not available, more consumers would seek prescriptions, causing a surge in office visits that would require 56,000 additional full-time medical professionals to accommodate.
9. OTC medications are a critical component in advancing consumer health because they allow

### Table 4: OTC medication for geriatric patient

<table>
<thead>
<tr>
<th>Category</th>
<th>Drug name/API</th>
<th>Reason for avoiding them</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAIDs</td>
<td>Digoxin (lanoxin), Aspirin, Clopidogrel (plavix), Dabigatran (paradaxa), Warfarin (Coumadin), Ticlopidine (ticlid), Dipyridamole (persantine)</td>
<td>It can be toxic in older adults &amp; people whose kidneys do not work well. Can increase the risk of indigestion, ulcers and bleeding in your stomach or colon, it can also increase blood pressure, affect kidneys and make heart failure</td>
</tr>
<tr>
<td>Muscle relaxants</td>
<td>Cyclobenzaprine (flexeril), Methocarbamol (robaxin) and Carisoprodol (soma)</td>
<td>Can increase the risk of falls, &amp; cause constipation, dry mouth, &amp; problems in urinating. Can also leave your feeling groogy &amp; confused.</td>
</tr>
<tr>
<td>Medications Used for anxiety &amp; insomnia</td>
<td>Benzodiazepines-such as Diazepam (valium), Alprazolam (xanax), Chlordiazepoxide (librium) Sleeping pills such as Zaleplon (sonata) &amp; Zolpidem (ambien)</td>
<td>Can increase the risk of falls as they can make confused, since body takes long time to get rid of these drugs, it makes feel like groggy &amp; sleepy for a long time</td>
</tr>
<tr>
<td>Anticholinergic drugs</td>
<td>Tofranil, Elavil, Bentyl</td>
<td>Can cause confusion, constipation, problems, urinating, blurry vision &amp; low blood pressure.</td>
</tr>
</tbody>
</table>
people to treat or manage many health conditions conveniently and successfully.[20]

10. According to a research study-$1 spent on OTC medications = $6-7 in savings for the US health system due to fewer physician visits and reduced spending on more expensive care.

11. 86% consumers believe that OTC medicines reduced their healthcare costs as they are affordable.

12. Research has estimated that consumers and taxpayers could save $5.2 billion annually through increased self-care, including use of OTC medicines and subsequently avoidance of unnecessary visits to primary care physicians.

13. In a survey of US primary care physicians, 75% would recommend OTC products prior to a medicine for minor ailments as cough, cold, pain, allergies and acid eflux/upset stomach.

Indian OTC drugs market: An overview

1. India ranks 11th in terms of OTC market size globally.[23]

2. Indian OTC drugs market is growing at a rate of 23% and is estimated to be worth $1,793 million.[23]

3. Indian market is large and highly fragmented that almost 70,000 brands are competing for customer’s wallet. Brands like- Revival, Crocin, Smyle, Glycodin have positive images and hence established customer loyalty as well. [23]

4. ‘I-pill’- a Piramal Healthcare Ltd product (which has strong consumer brand- lacto calamine skin care range, supractiv complete, saridon and polycrol) features in the list of top 300 pharmaceutical products and had sales of Rs 309.2 million (30.92 crores) as per ORG IMS in its first year of market introduction[23]

5. The Indian Pharmaceutical market is expected to touch us $74 billion sales by 2020. [24]

6. The list of drugs in India is increasing day by day, some of the top OTC brands in India are- Dabur Honitus lozenges, Cough syrups, Vicks vaporub, Zandu balm, Iodex, Moov, Cough drops and lozenges etc [18].

7. Key categories of medicines with high OTC potential in India are [18, 25],
   - vitamins and mineral
   - cough and cold
   - gastrointestinal
   - analgesics/dermatological

Nowadays even anti-obesity drugs and anti-stress candies are emerging as OTC medicines in India [18]

8. The urban India is catching up with the concept of OTC more as compared to rural areas and reasons are the advent of technology, improving literacy levels, increasing healthcare awareness and high work stress levels.[18]

9. India’s drug industry is one of the country’s most important economic engines, exporting $15 billion in products annually, and some of its factories are world-class.[26]

10. India is the second-largest exporter of over-the-counter and prescription drugs to the United States [26]. See (table 5) for categories of OTC and their brands in Indian market
Table 5: Categories of OTC and their brands in Indian market

<table>
<thead>
<tr>
<th>Category</th>
<th>Brands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antacids</td>
<td>Axid AR, Gaviscon chew tab &amp; liquid, Maalox, Pepcid, Mylanta, Pepcid AC, Tagamet, Zegerid OTC</td>
</tr>
<tr>
<td>Cough Suppresant</td>
<td>Delsym, Tussin, PediaCare, Robitussin, Triaminic</td>
</tr>
<tr>
<td>Cough/ Cold / Allergy Combinations</td>
<td>Advil Cold &amp; Sinus, Advil Multi-Symptom, Coricidin HBP Chest Congestion, Vicks Formula 44</td>
</tr>
<tr>
<td>Corn / Callus Remover</td>
<td>Corn &amp; Callus remover, Salicylic Acid Solution</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>Imodium AD, Kapectate, Pepto-Bismol</td>
</tr>
<tr>
<td>Expectorants</td>
<td>Diabetic Tussin Ex, Mucinex, Robitussin Chest Congestion, Vicks</td>
</tr>
<tr>
<td>Gas Relief</td>
<td>Beano, Gas-X, Mylanta Gas, Simethicone</td>
</tr>
<tr>
<td>Migraine</td>
<td>Advil Migraine, Motrin Migraine</td>
</tr>
<tr>
<td>Pain and Fever</td>
<td>Aspirin</td>
</tr>
<tr>
<td>Pain and Inflammation</td>
<td>Advil, Aspirin, Ibuprofen</td>
</tr>
<tr>
<td>Proteins</td>
<td>Proteinex</td>
</tr>
</tbody>
</table>

Conclusion

As self-care with OTC drugs has evolved, the switching of drugs from prescription to non-prescription status has produced important benefits, creating more self-reliant consumers through novel selfcare therapeutics, significant cost savings to the health care system, expanded markets for companies, enhanced science for regulatory decisions, and a more consumer friendly label for all OTC agents and predictable drug approval process.

Conflict of interest

The authors declare that there is no conflict of interest to reveal.
References


