

Evolution of over the counter drugs (OTC medications/Non-prescription drugs) during last 10 years and the effective use of over the counter medications during pregnancy

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ABSTRACT: An over the counter medication is a drug that can be purchased without prescription that means these are legally allowed to be sold by pharmacists without needing for any prescription. Over the counter drug review was first initiated by the FDA in 1972 and then over the counter drug development progressed to a stepwise process of CDER evaluations by the office of non-prescription drugs. This review mainly discuss the current knowledge about the over the counter drugs among the public and pregnant woman and growing factors as well as evaluation studies of over the counter drugs in recent years.

KEYWORDS: over the counter, non-prescription drugs, acetaminophen, ibuprofen, dextromethorphan, anti-histamine, loratadine, acetaminophen, calcium carbonate, guaifenesin, ibuprofen, aspirin, prenatal vitamins, H₂-antagonists, non-sedating, FDA, anti-pyretic, laxative, nasal decongestants, antifungal, R_x, first trimester, allergies, antacids, simethicone, anti-diarrheal, heartburn, upset stomach, insomnia, itching/rash, vaginal anti fungal, pain relief, yeast infections

INTRODUCTION

OTC drugs are medications that are safe and effective for use by the general public without seeking treatment by a health professional. Popular examples include pain relievers like acetaminophen (Tylenol) and ibuprofen (Advil, Motrin), cough suppressants such as dextromethorphan (Robitussin) and antihistamines like loratadine (Claritin 24H). These drugs are usually located on shelves in pharmacies, grocery stores, and even in gas stations. OTC medicines treat a variety symptoms due to illness including pain, coughs and colds, diarrhea, heartburn, constipation, acne, and others.

Over the counter medications used by pregnant woman is common and it is evidenced by many studies also. A study in the journal of obstetrics and Gynaecology (2003) examine the prescription ,over the counter and herbal medicines

use in the rural, obstetric population and found that 92.6% self-medicated with at least one OTC product and 45.2% used herbals. In addition 20.8% took five or more over the counter medications during pregnancy and they noted that trend of increased use as pregnancy progressed, especially in case of acetaminophen, calcium carbonate, cough drops and guaifenesin and other over the counter medications like ibuprofen, aspirin, prenatal vitamins, H₂ - antagonists and non- sedating anti histamines.

Background and regulatory pathways for marketing over the counter drugs :

The Food and Drug Administration (FDA) has regulated most over-the-counter (OTC) drugs— that is, drugs available without a prescription— through the OTC monograph process. FDA has described an OTC monograph as a "rulebook" for marketing safe and effective OTC drugs, such as aspirin, cough and cold medicine, and hand sanitizer. According to FDA officials, the new process for regulating OTC drugs included in the CARES Act could improve FDA's ability to address identified safety risks in a more timely and efficient manner in the future. The act established an expedited process to address safety issues that pose an imminent hazard to public health or to change a drug's labelling to mitigate a significant or unreasonable risk of a serious adverse event.

The difference between over the counter and prescription drugs may not be always similar, for example in New Zealand low dose ibuprofen (200mg) is used as OTC drug for treating minor pains but high doses like 400,600 & 800mg is prescription medicine used for severe pain associated with arthritis.

Usage of over the counter drugs :

The OTC drug market depends on basis of region, product type, route of administration, dosage form and distribution channel, like..

By Product Type:

Cough, Cold and Flu Products
 Analgesics
 Dermatology Products
 Gastrointestinal Products
 Vitamins, Minerals and Supplements (VMS)
 Weight-loss/Dietary Products
 Ophthalmic Products
 Sleeping Aids
 Others

By Route of Administration:

Oral
 Parenteral
 Topical
 Others

By Dosage Form:

Tablets and Capsules
 Liquids

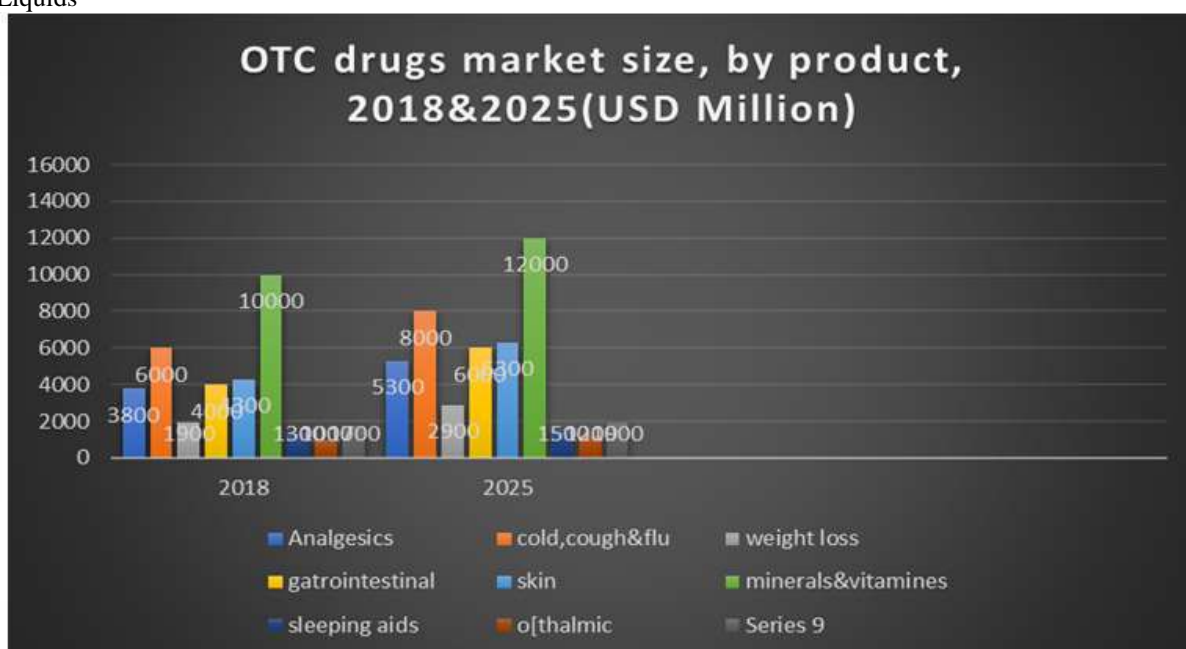
Ointments
 Others

By Distribution Channel:

Hospital Pharmacies
 Retail Pharmacies
 Online Pharmacies
 Others

By Region:

In India
 North America: (United States, Canada)
 Asia Pacific: (China, Japan, South Korea, Australia, Indonesia, Others)
 Europe: (Germany, France, United Kingdom, Italy, Spain, Russia, Others)
 Latin America: (Brazil, Mexico, Others)
 Middle East and Africa

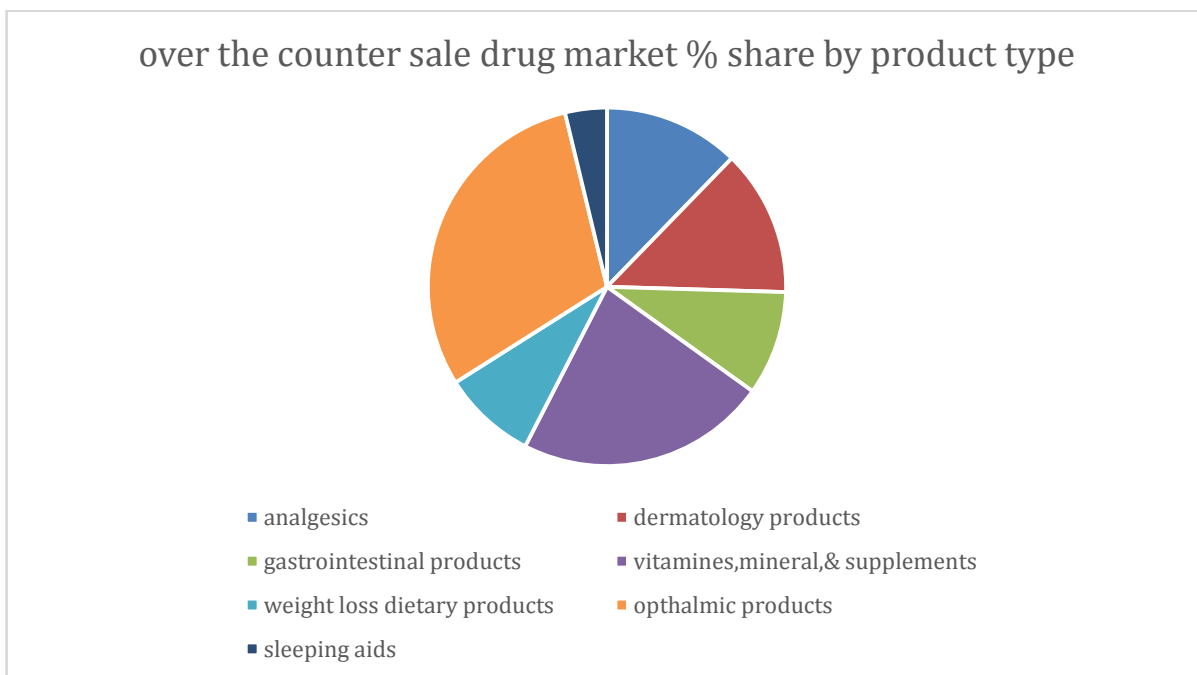


Assessment of drug interactions or side effects related to over the counter drugs:

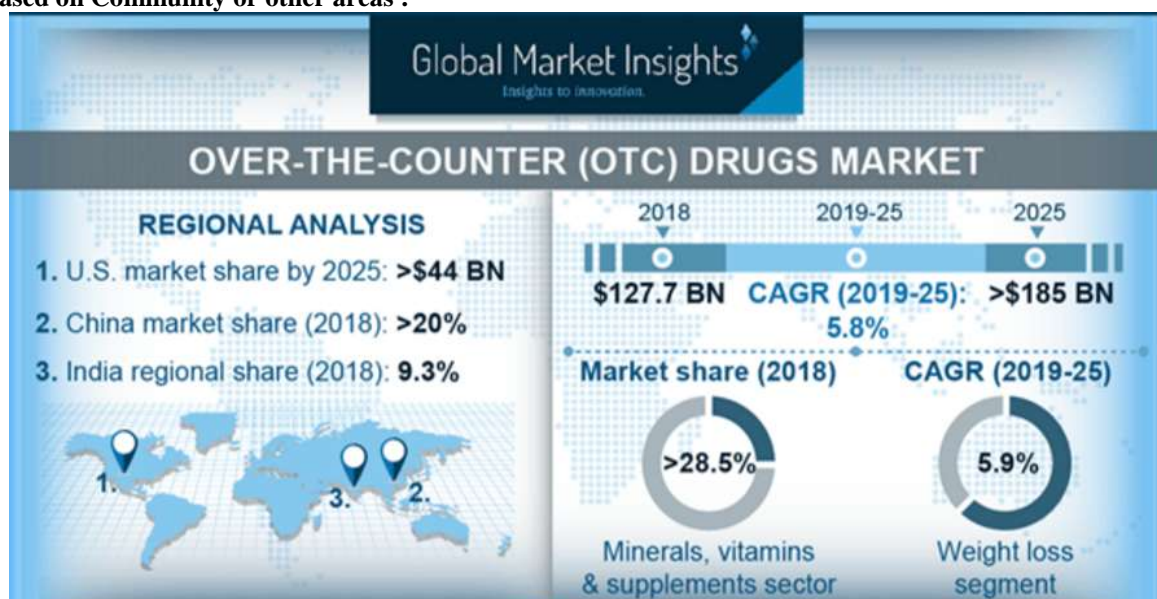
Drug related problems such as adverse drug reactions ,drug-drug interactions, idiosyncratic reactions and hypersensitivity reactions remains a major challenge in clinical practice as well as in over the counter drug usage. Potential drug interactions (PDDI) are observed to be one of the most frequently appearing challenge that alter the pharmacokinetic and pharmacodynamic of the drugs.

List of over the counter drugs according to their approval for usage :

OTC medications mainly classified into two categories, first category includes medicines which have been under non prescription category since they were introduced, second category is initially they were introduced as prescription drugs and later they shifted to the over the counter medicines.



Based on Community or other areas :



(OTC) drugs are chosen by regulatory agencies in many countries to guarantee that they contain chemicals that are safe and effective when taken without the supervision of a Growth Factors for OTC medications:

The prescription drugs, on the other hand, can only be sold to consumers who have a valid prescription. Over the counter (OTC) drugs are the medicines that is sold directly to a consumer without any kind of prescription from a healthcare providers

or doctors. Over the counter physician. The active pharmaceutical ingredient (API) of over the counter (OTC) drugs is usually regulated rather than the end product. Governments can freely create chemicals, or combinations of ingredients, into proprietary mixes by controlling APIs rather than specific medication formulations.

In recent years, the demand for over the counter (OTC) drugs has increased due to the COVID-19 pandemic. The cough and cold cases

increased due to pandemic. The sale of cold and cough remedies was high during the outbreak. The consumers brought over the counter (OTC) drugs through online pharmacies. This is was due to social distancing norms and guidelines. The revenue and profit of online pharmacies increased during the epidemic of coronavirus. Such instances result into the growth of over the counter (OTC) drugs market.

The increased geriatric population, who are more susceptible to cough and cold, increased vehicle pollution, increased R&D activities leads to the high demand for over the counter (OTC) drugs in the market. An increase in the number of cough and cold cases, the development of sophisticated products, and the adoption of efficient treatments are expected to boost the overall market demand for over the counter (OTC) drugs.

In the future years, the over the counter (OTC) drugs market will be driven by the increasing availability and manufacturing of over the counter (OTC) drugs for a wide range of common illness problems. The demand for medicines is fuelled by the recurrence of common colds and flu. Furthermore, the increased awareness and demand for weight loss and vitamin supplements products would significantly boost the over the counter (OTC) drugs market growth. Over the counter (OTC) drugs demand is expected to be fuelled by cost-benefit analysis, positive results, and increased accessibility during the forecast period.

The development of knowledge about general health problems, as well as advancements in the healthcare and pharmaceutical industries, are driving the global over the counter (OTC) drugs and dietary supplements market. Furthermore, an increasing trend among individuals to choose over the counter (OTC) drugs for minor illnesses contributes to market growth. On the other hand, the Food and Drug Administration (FDA) strict

restrictions governing the safety and efficacy of over the counter (OTC) drugs stifle the market growth during the forecast period.

Self medication with over the counter medicines among the population in India:

According to the contract pharma magazine they estimated that by 2024 , OTC dugs market revenue exceed \$178B and this growth is driven by massive demand for health supplements and analgesics. With well informed consumers learning toward self medication and demand cost reducing in healthcare OTC drug market outlook has been witnessing a dramatic transformation in the last few years. Since OTC drugs do not require a doctor's visit or a known prescription, these drugs are quite cost- and time-effective. Many regulatory bodies across the globe that are responsible for deciding which drugs should be available OTC and which should be sold only based on a prescription, are now shifting an increasing number of medicines from the prescription to OTC segment. A study by CHPA in fact, had stated decades earlier, that this paradigm switch is likely to save close to \$20 billion every year. The backdrop of cost-saving coupled with public demand has indeed propelled the OTC drugs industry that is expected to depict a profitable growth path over 2017-2024.

The Union government, for the first time, has proposed to introduce over-the-counter (OTC) drugs in India through an amendment in the Drugs and Cosmetics Rules and allow their sale in the retail market without doctors' prescription.

A draft notification issued by the Union health ministry has proposed that the 16 drugs, which include common antipyretic medicine such as paracetamol 500 mg, some laxatives, nasal decongestants and topical antifungal creams be included in the OTC drug category.

Table:1: The Sixteen commonly used drugs proposed for over the counter sale by Indian Governmentrecently

Drug	Category/uses
Chlorohexidine mouthwash	Glinivitis
Povidine iodine	Antiseptic and disinfectant
clotrimazole	Antifungal
Clotrimazole dusting powder	Antifungal
Dextromethorphan hydrobromide lozenge	Cough
Diphenhydramine capsules	Antihistamine/antiallergic
Diclofenac ointment,cream,gel	Analgesic
Paracetamol 500mg	Anti pyretic
Sodium chloride nasal spray	Nasal decongestant
Oxymetazoline nasal solution 0.05%	Nasal decongestant
Ketoconazole shampoo	Anti dandruff

Lactulose solution 10mg	Laxative
Benzyl peroxide	Anti bacterial for acne
Calamine lotion	Anti septic
Xylometazoline hydrochloride	Nasal decongestant
Bisacodyl tablet 5mg	Laxative

Table:1

High awareness regarding over-the-counter medicines will increasing the market demand:

The U.S. OTC drugs market held 94.4% revenue share of the North America region in 2020. High responsiveness rate to availability and usage of non-prescription drugs in the country has propelled the market revenue. Moreover, certain American organizations are also educating the younger population about the safe use of such medications to avoid drug abuse. There are several industry leaders operating the nation that have strong foothold in the market. Thus, with rising approvals, product introductions, and expansion of product distribution channels, the U.S. region will observe lucrative growth over the forecast period.

Use of over the counter medications by pregnant woman:

Although some medications are considered safe during pregnancy, the effect of other medications on the unborn baby are unknown. According to some recent surveys approximately two thirds of woman taking one or more non-prescription medications during pregnancy. Yet most medications have not been adequately studied for their safety during pregnancy, so therefore it is very important to pay special attention to medications take while pregnancy, especially during the first trimester, because it is a crucial time of development for the baby. If you are taking prescription drugs or any new medications you can approach to your doctor to make sure about the risks and benefits of those drugs. But here we are providing some necessary information about which over the counter drugs are safe during pregnancy. But anyone should not take any over the counter medication unless it is necessary and before taking over the counter medication should follow the package directions and labelling which are present on the medications. Here we have collected some information about safe medications which can use during pregnancy from the literatures And according to the another primary study approximately 96.9% of pregnant woman taken at least one medication while pregnancy, excluding prenatal vitamin and iron supplements they found 62.8% used over the counter medications and 4.1% used herbals.

Additionally 33.5% used two or more medications and 13.6% used four or more drugs during their pregnancy period.

Increasing trend of self-medication will drive demand for OTC drugs:

Growing trend of switching from prescription (Rx) to non-prescription (OTC) in developed countries will stimulate the market growth in the coming years. Companies are switching prescription drugs to OTC drugs in order to improve and rise self-medication. Cost-effectiveness of OTC drugs further favours the demand for these drugs. The U.S. FDA approved around five prescription to OTC drugs' switch in 2020. With growing awareness about OTC drugs and self-identification of diseases, the demand for over-the-counter medicines will rapidly grow in the forecast timeframe. However, risk of counterfeit drugs and overuse of drugs may limit the market value up to some extent.

Reasons for self medication and prevalence of self medicationpractices in India :

According to the some philosophers Indians have mind set that the doctor which they are concerning for their medication will increase their problem instead. Then after few days of improper medication doctor will cure them better and make them fit!! I think the doctor are the reason themselves coz they actually do so for some money and make people suffer for several days more.

Basically for instance if one is opting medical field he or she never desires to make people fit and cure them better being a doctor, their priority says in this field they make more money.

Nowadays people are well known and educated so they can cure their disease by just consulting the doctor without suffering for more days with their disease. Self medication is necessary but on particular levels. Self-medication is often due to an underlying issue, which could be a physical health problem, mental health issue, psychological distress or stress If we consider the causes for self medication, here we include that

- Healthcare cost
- Waiting time

- Lack of awareness
- Gender
- Socioeconomic status
- Influence of advertisements
- Minor problems
- Ease of availability of medicines
- Misbelief of patients that illness can be managed better with self-care

Evolution of OTC drugs in last 10 years:

An OTC drug (over the counter drug) is that can be purchased without prescription ,before an OTC drug approved for sale, FDA must first recognize it as safe and effective and check the

labelled directions on the container with regarded to the dose , frequency, precautions and contraindications and duration of therapy are followed, The FDA approved many drugs after the expiration of the manufactures patent on the prescription drug. It is very important that OTC drugs have adequate product labelling written in easily understanding terms, for the consumer proper using because as there is no communication with the pharmacist or any physician.

A part from the FDA labels there are numbers are information resources are available for the determination of safety of medications during pregnancy, below

Table:2 listing the trustworthy resources to utilize while seeking information about medications and supplements.

Resource	Summery
Daily Med	Many unapproved medicines such as vitamins also described in DailyMed. It also provides information about human drugs, animal drugs, and information related to the indications, doses, contraindications, precautions, warnings, ADRs, and so many other specific information.
Medline Plus	A wide variety of information is available in this website, of special note Medline plus has special section of information on herbs and supplements
Package Inserts	When FDA approves a drug it produces a detailed label of that product this is called package inserts. There are number of ways to access a package insert.
Drugs @FDA	This is useful resource if you want information about approval dates, information about labelling updates or different marketing statuses of drugs.
NIH office of dietary supplements(ODS)	The ODS one of more robust online resource for dietary supplements, under the health information tab readers can track the facts and watch videos about what individuals should consider when start a new dietary supplements and there is a frequently asked questions page for the readers.
PubMed	If you want to access information related to a trial, this is very useful. It provides all sorts of published trials, case reports, retrospective analysis etc.
FDA CDER Division of Drug Information	It is one of the more helpful divisions of FDA. DDI has a strong media presence to share reliable drug information (facebook and twitter) and it even hosts a number of podcasts.

Table:2

In Table No 3: we have collected some practice based student research survey on description and frequency of over the counter medications used by pregnant woman, in that survey around sixty one pregnant woman are participated and we collected the given data.

Have you taken any OTC medications for...	Yes (%)	Drugs	% of Total
Pain, Headache, or Fever	68.9	Acetaminophen	67.2

		Aspirin	4.9
		Ibuprofen	4.9
Cold, Cough, or Sore Throat	26.2	Cough drops	13.1
		Sudafed	9.8
		Afrin nasal spray	4.9
		Roditussin	1.6
		Herbal nasal spray	1.6
		Tylenol cold	1.6
Heart burn or acid reflux	47.5	Tums	36.1
		Ranitidine	8.2
		Famotidine	3.3
		Omeprazole	3.3
		Mylanta	1.6
		Maalox	1.6
		Pepto Bismol	1.6
		Coral calcium	1.6
Constipation, diarrhea or upset stomach	18.0	Docusate	9.8
		Pepto bismol	1.6
		Metamucil	1.6
		Imodium	1.6
		Milk of magnesia	1.6
		Fiber	1.6
		Senna	1.6
Allergies	11.5	Diphenhydramine	8.2
		Loratadine	3.3
		Cromolyn	1.6
Vitamins	91.8	Prenatal	88.5
		Vitamin D	32.8
		Calcium +vitamin D	23.0
		DHA	21.3
		Folic acid	9.8
		Multivitamin	6.6
		Vitamin B6	4.9
		Iron	3.3
		Calcium	1.6
		Zinc	1.6
Vitamin A	1.6		
Herbals or supplements	14.8	Ginger	8.2
		Melatonin	1.6
		Slippery Elm	1.6
		Valerian	1.6
		Fish oil	1.6
		Echinacea	1.6
other	6.6	Doxylamine	3.3
		Cortisone cream	1.6
		Monistat	1.6
		Dramamine	1.6

Table:3

What OTC Medicines are Safe During Pregnancy?

However for the ethical reasons a majority of clinical trials do not include pregnancy woman, therefore limited evidence is available to help evaluate the over the counter medications during pregnancy. Generally Pregnancy brings a lot of ailments and complaints. Luckily some over the counter remedies are safe to use. The following list

isn't comprehensive, it should give you a general idea about what's okay to take during pregnancy to relieve common complaints. Again, discuss any medications you take with your doctor.

Allergies
 Antihistamines that include Chlorpheniramine, Loratadine, and Diphenhydramine (Chlor-Trimeton, Alavert, Claritin, Benadryl)

Table No:4 OTC Decongestants, Expectorants, and Nonselective Antihistamines in Pregnancy

Drug name	FDA Pregnancy risk classification	Drug class	Crosses Placenta?	Use in pregnancy
Chlorpheniramine (Chlor-Trimeton)	B	Antihistamine	Not known	Antihistamine of choice
Pseudoephedrine hydrochloride (Novafed)	B	Sympathomimetic decongestant	Not known	Oral decongestant of choice, possible association with gastroschisis
Guaifenesin (Humibid L.A.)	C	Expectorant	Not known	May be unsafe in first trimester
Dextromethorphan hydrobromide (Benylin DM)	C	Non-narcotic antitussive	Not known	Appears to be safe in pregnancy
Diphenhydramine (Benadryl)	B	Antihistamine /antiemetic	Yes	Possible oxytocin-like effects at high dosages
Clemastine fumarate (Tavist)	B	Antihistamine	Not known	Unknown safety profile

Table:4

OTC = over-the-counter ; FDA = U.S. Food and Drug Administration.

*- Possible increased risk of neural tube defects.

Table:5 OTC Antacids, Simethicone, and H2-Receptor Selective Antihistamines in Pregnancy

Drug name	FDA pregnancy risk classification	Drug class	Crosses placenta?	Use in pregnancy
Aluminum hydroxide/magnesium hydroxide (Maalox)*	B	Antacid	Not known	Generally regarded as safe
Calcium carbonate (Turns)	C	Antacid	Not known	Generally regarded as safe
Simethicone (Mylanta Gas)	C	Antiflatulent	No	Generally regarded as safe
Cimetidine (Tagament)	B	Antihistamine	Yes	Preferred after antacids; generally regarded as safe
Ranitidine (Zantac)	B	Antihistamine	Yes	Preferred after antacids; generally regarded as safe
Nizatidine (Axid)	C	Antihistamine	Yes	Not recommended
Famotidine (Pepcid)	B	Antihistamine	Yes	Probably safe, data needed

Table:5

OTC = over-the-counter; FDA = U.S Food and Drug Administration.

*-Contains magnesium sulfate.

Table:6 :OTC Antidiarrheal Medications in Pregnancy

FDA category risk classification by trimester(1 st ,2 nd ,3 rd)	Drug name	Drug class	Crosses placenta?	Use in pregnancy
B/B/B	Kaoline and pectin(kaopectate)	Antidiarrheal	No	Antidiarrheal of choice (not absorbed)
C/C/D	Bismuth subsalicylate(peptobismol)	Antidiarrheal	Yes	Not recommended(salicylate absorption)
B/B/B	Loperamide(Imodium)	Antidiarrheal	Not known	Probably safe*
C/C/C	Atropine/diphenoxylate(lomotil)	Antidiarrheal	Not known	Not recommended(adverse animal studies)

Table:6

OTC = over the counter;
 Heartburn, upset stomach, gas/bloating
 Antacids (Tums, Mylanta, Rolaids, and Maalox).
 Simethicone for gas pain (Gas-X, Mylanta Gas, Mylicon, and Maalox Anti-Gas)
 Insomnia

Diphenhydramine (Benadryl, Nytol) and Doxylamine succinate (Unisom Nighttime Sleep-Aid)
 Itching/rash
 Hydrocortisone (Cortaid, Lanacort).

Table:7: OTC Topical Vaginal Antifungal Medications in Pregnancy

Drug name	FDA pregnancy risk classification	Drug class	Crosses placenta	Use in pregnancy
Butaconazole (femstat)	C	Imidazole anti fungal	Not known	Probably safe
Clotrimazole(lotrimin)	C	Imidazole anti fungal	Not known	Safe in second and third trimesters(human trials) first trimester probably safe
Miconazole (monistat)	C	Imidazole anti fungal	Not known	Probably safe
Tioconazole(vagistat-1)	C	Imidazole anti fungal	Not known	No data

Table:8

Pain relief, headaches, and fever
 Acetaminophen (Tylenol, Anacin Aspirin-Free)

Table:9: Use of OTC Pain Medications in Pregnancy

Drug name	FDA pregnancy risk classification by trimester (1st/2nd/3rd)	Drug class	Crosses placenta?	Use in pregnancy

Acetaminophen (Tylenol)	B/B/B	Non-narcotic analgesic/antipyretic	Yes	Pain reliever of choice
Aspirin	D/D/D	Salicylate analgesic/antipyretic	Yes	Not recommended except for specific indications*
Ibuprofen (Advil, Motrin)	B/B/D	NSAID analgesic	Yes	Use with caution; avoid in third trimester†
Ketoprofen (Orudis)	B/B/D	NSAID analgesic	Yes	Use with caution; avoid in third trimester†
Naproxen (Aleve)	B/B/D	NSAID analgesic	Yes	Use with caution; avoid in third trimester

Table:9

Yeast Infections

Tioconazole (Monistat 1, and Vagistat 1), Clotrimazole (Gyne-Lotrimin 3, Lotrimin AF), Miconazole (Monistat 3, Desenex). Some antifungal products shouldn't be used during pregnancy. Check with your doctor and carefully check labels.

In India due to easy availability of drugs coupled with inadequate health services, increased proportion of drugs are used as self medications for common complaints and infective conditions as compared to prescribed drugs. Hence these consumers always face the threat of adverse drugs reactions and drug interactions. While many OTC drugs can be used during pregnancy under a physician's supervision, some are known to be unsafe. As indicated on product labels, women who are pregnant, who may be pregnant, or who are nursing should consult a doctor before taking OTC medication.

Role of pharmacist :

Being a pharmacist , pharmacists have played an important role in recommending OTC products, by asking their patients appropriate questions. Patient can learn self medication is appropriate or referral is needed. Pharmacists are key roles in the growing of OTC products recommendations. Because they are very accessible and truly trusted by consumer and pharmacists are accepted with the neighbourhood health team. If OTC products are appropriately used, these are very effective and saves money while improving outcomes. Now a days OTC drug education is the important part of pharmacy education and they have been trained to make OTC product recommendations and they are comfortable in their

role and they give influence to grow also.

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REFERENCES

- [1]. Over-the-Counter Medications in Pregnancy (aafp.org)
- [2]. Over-The-Counter Medication Use in Older Adults | Journal of Gerontological Nursing (healio.com)
- [3]. Nonprescription Drug Abuse - Addison J. Conca, David R. Worthen, 2012 (sagepub.com)
- [4]. Safety of Over-the-Counter Medications in Pregnancy - PubMed (nih.gov)
- [5]. Use of over-the-counter medications during pregnancy - American Journal of Obstetrics & Gynecology (ajog.org)
- [6]. Utilization of over-the-counter drugs during pregnancy - PubMed (nih.gov)
- [7]. Over the counter drugs - PubMed (nih.gov)
- [8]. [Must I prescribe over-the-counter drugs?] - PubMed (nih.gov)
- [9]. The safety of over-the-counter drugs: some reflections and unanswered questions - PubMed (nih.gov)
- [10]. Use of over-the-counter medications during pregnancy - PubMed (nih.gov)
- [11]. OTC Drugs Becoming More Like Consumer Goods —Business Opportunities Extending to Other Industry Players— (mitsui.com)



- [12]. Over the counter drug list
(aetnabetterhealth.com)
- [13]. Exclusive | Government proposes over-the-counter sale of 16 commonly used medicines (moneycontrol.com)
- [14]. Over-the-counter medicines: Global perspective and Indian scenario - PMC (nih.gov)
- [15]. Over-the-Counter OTC | Nonprescription Drugs | FDA
- [16]. Over-The-Counter Drugs: Information on FDA's Regulation of Most OTC Drugs | U.S. GAO