A Review of Over-The-Counter (OTC) Drug Therapy and Toxic Potential

Dr. Dilip Kumar Gupta*1, Dr. B.K. Razdan2, Dr. Meenakshi Bajpai3

Abstract- The purchase of over-the-counter (OTC) or nonprescription medicines from pharmacies, supermarkets and other retail stores as well as online without a prescription can help consumers' self-manage symptoms. However, some OTC medicines may be abused, with addiction and harms being increasingly recognized. OTC medicines have played a significant role in expanded access to safe and effective treatments in developing regions of the world. Many people in these regions do not have access to health services and rely heavily on self-care and self-medication, and OTC medications provide valuable resources to address health conditions. Several sources express concern about the inaccessibility of accurate OTC drug information to the consumer. Indeed, even the Food & Drug Administration (FDA) has occasional difficulty obtaining reliable facts on both the numbers and formulae of such products. Several studies indicate that consumers acquire information about their home remedies through advertising, friends and relatives, physicians, pharmacists, and product labels. Testing of the safety and efficacy of non-prescription remedies has proved to be controversial, especially when considering the ramifications of the placebo effect. Different surveys report widespread misuse of OTCs by consumers through overuse, taking several drugs concurrently, and using home remedies to treat potentially serious diseases. In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated by the Drugs and Cosmetics Act (DCA) and its subordinate legislation, the Drugs and Cosmetics Rules (DCR). This review describes the current knowledge and understanding of OTC medicine abuse.

Keyword: OTC medicines, Non-prescription medicines, Food & Drug Administration, Drugs and Cosmetics Act, self-care and self-medication.



OTC Drugs' means drugs legally allowed to be sold 'Over the Counter', i.e. without the prescription of a Registered Medical Practitioner [1]. These medicines treat common, self-treatable health conditions and symptoms such as the common cold, minor pain, allergies, and other conditions that impact large segments of the population [2]. OTC medicines provide easier access to treatment options for common conditions, offering not only convenience, but also timely treatment and relief for sudden symptoms or minor ailments [3].

- ¹ Associate Professor, RKGIT [Pharmacy], Ghaziabad. U.P.- 201003, India. Email ID: <u>kumarjai24sep@gmail.com</u>
- ²Former HOD, BIT Mesra, Ranchi

 ³Institute of Pharmaceutical Research, GLA University, Mathura

The range of medicines available is often more restrictive compared to prescribed medicines [Table 1 & 2], and there are often limitations to indications and doses, although there has been a trend towards increasing deregulation of medicines from prescription to OTC supply and most recently availability from Internet pharmacies [4]. There has been a tendency for the public to perceive OTC medicines to be safer than prescription medicines [5, 6, 7], but it has been recognized that OTC medicines have the potential for harm as well as benefit [8]. This may result in what has been variously referred to as the misuse or abuse of OTC medicines and their potential to cause addiction and dependency. A number of specific OTC medicines and therapeutic groups have been implicated and in a recent review for doctors, for example, Lessenger and Feinberg (2008) suggested medicines such as stimulants, laxatives, sedatives and dissociative substances

such as dextromethorphan as being liable to abuse. They noted that in relation to abused drugs, "the literature is sparse about OTC medicines" and their review tellingly omits opiate-based OTC analgesics. The latter are available for purchase in many countries and combine codeine dihydrocodeine with either ibuprofen paracetamol and have led to particular concerns about addiction and also gastric or hepatic damage, respectively [9, 10].

2 LEGAL ASPECTS OF OTC

2.1 Described by the FDA

"Over-the-counter (OTC) medicines are drugs you can buy without a prescription. Some OTC medicines relieve aches, pains and itches. Some prevent or cure diseases, like tooth decay and athlete's foot. Others help manage recurring problems, like migraines. In the United States, the Food and Drug Administration decides whether a medicine is safe enough to sell over-the- counter. Taking OTC medicines still has risks. Some interact with other medicines, supplements, foods or drinks. Others cause problems for people with certain medical conditions. If you're pregnant, talk to your healthcare provider before taking any medicines. It is important to take medicines correctly, and be careful when giving them to children. More medicine does not necessarily mean better. You should never take OTC medicines longer or in higher doses than the label recommends. If your symptoms don't go away, it's a clear signal that it's time to see your healthcare provider [11, 12, 13, and 14].

2.2 Described by the Drug & Cosmetics Act 1940/ Rules 1945

All drugs except those listed in Schedule K of the D&C Rules, 1945, need a licence (in terms of Rule 65), permitting them to be sold. Those permitted to sell drugs under a licence can sell two types of drugs, namely, Prescription Drugs and Non Prescription Drugs. The Prescription Drugs are those drugs, which are listed in Schedule H, which is titled as Prescription Drugs. In accordance with Rule 65(9), such drugs can be sold only on the basis of a prescription issued by a Registered Medical Practitioner as defined in Rule 2(ee) of the D&C

Rules, 1945. In view of the Supreme Court's judgment in Mukhtiar Singh case, the definition of a Registered Medical Practitioner as defined in Rule 2(ee) of the D&C Rules, 1945, now means, for practical purposes, a person having a degree in modern medicine. In terms of Rule 123, drugs listed in Schedule K of the D&C Rules, 1945, do not need a licence for sale if sold by shop other than a chemist's shop. Drugs in Schedule K include the following:

- A. Drugs not intended for medicinal use
- B. Quinine and other antimalarial drugs
- C. Magnesium sulfate
- D. Substances intended to be used for destruction of vermin or insects, which cause disease in human beings or animals viz. Insecticides and Disinfectants.
- E. Household remedies, namely:
 - i. Aspirin tablet
 - ii. Paracetamol tablets
 - iii. Analgesic balms
 - iv. Antacid preparations
 - v. Gripe water for use of infants
 - vi. Inhalers, containing drugs for treatment of cold and nasal congestion
 - vii. Syrups, lozenges, pills and tablets for cough.
 - viii. Liniments for external use
 - ix. Skin ointments and ointments for burns
 - x. Absorbent cotton wool, bandages,
 - xi. absorbent gauze and adhesive plaster.
 - xii. Castor oil, liquid Paraffin and Epsom salt.
 - xiii. Eucalyptus oil
 - xiv. Tincture iodine, Tincture Benzoin Co. and Mercurochrome solution in containers not exceeding 100 ml.
 - xv. Tablets of Iodochlorohydroxy quinoline -250 mg.
- F. Contraceptives
- G. Cosmetics
- H. Ophthalmic ointments of the tetracycline group of drugs
- I. Hair fixers
- J. Radio pharmaceuticals
- K. Tablets of chloroquine salts

- Preparations applied to human body for the purpose repelling insects like mosquitoes
- M. Medicated dressings and bandages for first aid
- N. Oral rehydration salts
- O. White or yellow petroleum jelly IP (nonperfumed)
- P. Morphine tablets
- Q. First Aid Kit supplied along with motor vehicle by the manufacturer or its distributor at the time of first sale of vehicle
- R. Nicotine gum containing up to 2 mg of nicotine

In view of the above, it is clear that the term OTC drugs would mean, in the context of Indian laws, drugs in Schedule K. The main drugs in Schedule K have been listed above.

2.3 Health Care Professional Perspectives

Physicians recognize the important role OTC medicines play in treating patients and serving as a trusted, first line of defense for many minor ailments. In a survey of U.S. primary care physicians, 75 percent would recommend an OTC product prior to prescribing a medicine to relieve their patients' symptoms for ailments such as allergies, pain, cough and cold, and acid reflux/upset stomach [16].

Pharmacists are also a critical component to realizing the benefits of OTC medications. They assist patients by navigating the many product options and recommending the right medication for an individual's needs. Pharmacists are available to provide safety information by identifying possible drug interactions between OTC products or between an OTC product and a prescription drug, food, or dietary supplements [17]. They are the face of health care in the pharmacy; they provide unparalleled access to professional advice and deliver valuable consultation at the moment of a prescription or an OTC medication purchase. With the growth of pharmacy retail clinics, nurse practitioners are an additional advocate for selfcare.

Although the percentage of the world's population without access to essential medicines has fallen

from an estimated 37 percent in 1987 to around 30 percent in 1999, the total number of people without access remains between 1.3 and 2.1 billion people, [18] and these people rely heavily on the existence of OTC drugs that can be found in local stores. A number of studies have suggested that OTC medicines have significantly reduced the "time to treatment" for deadly infectious and parasitic diseases in countries where access to health facilities are poor. [19] These differences have also been shown to impact health expenditures for poor households, severity of disease, and even mortality. [20]

An important way to introduce novel new ingredients into the OTC market is by switching a product from prescription-only to OTC status. Today, hundreds of currently available OTC products use ingredients and dosages that were only available by prescription just a few decades ago. [22] Conditions that have expanded consumer treatment options include yeast infection, diarrhea, allergies, heartburn, smoking cessation, overactive bladder, and insomnia.

2.4 World Health Organization (WHO)

The World Health Organization has determined that it is appropriate to switch products to OTC status when they are widely used and have been proven safe over a sufficient period to determine that they can be entrusted for consumer use. [23] For example, OTC availability of nicotine replacement therapy (NRT) has resulted in a greatly reduced burden of diseases caused by tobacco smoking. Globally, 37 percent of smokers have tried an OTC NRT, leading to more people quitting smoking. [21] A recent study estimated that the impact of changing smoking cessation drugs to OTC status produces a 78-92 percent increase in utilization, and that the resulting reduction in smoking would be valued at between \$1.8 billion and \$2 billion per year. [24].

3 AYURVEDIC MEDICINES [25]

OTC proprietary drugs which are registered as 'Ayurvedic Medicines' (traditional Indian medicines containing natural / herbal ingredients) are also regulated by the DCA and DCR. However, they do not require a drug licence and can

therefore be sold by non-chemists. There is no price control on 'Ayurvedic medicines'. Some of the top OTC brands in India such as Vicks VaproRub, Amrutanjan Balm, Zandu Balm, Iodex, Moov Pain Cream, Itch Guard Cream, ENO Fruit Salt, Vicks Cough Drops, Halls Lozenges, etc., are registered as 'Ayurvedic Medicines' because of their plantbased natural active ingredients. Considering the above framework, key categories with OTC potential in India would be:

- Vitamins and minerals
- · Cough and cold
- Gastrointestinals
- Analgesics / Dermatological

4 PHARMACY TRAINING AND ATTITUDES

O.T.C. drugs require no pharmacists' consultation for selling. However, an active role and responsibility of pharmacists in promoting selfmedication is important. [26]

5 DOCTORS TRAINING AND ATTITUDES

A survey among doctors on O.T.C. medicines brought out following interesting responses:-

- ➤ 72% of doctors were willing to give an opinion on the O.T.C. medicines.
- ➤ 21% of doctors were willing to recommend/prescribe an alternative.
- Only 7% of doctors found it against their medical ethics to give advice on advertised brands.

In fact, if it is well-known & trusted brand, then they have no problem if it moves into O.T.C. domain and is directly marketed to consumers. [27]

6 CONSUMER ATTITUDES/RESEARCH

[28]

Indian consumers confidently self-treat a wide range of common ailments such as cough, cold, fever, pain, sprains, heartburn and diarrhea. When suffering from a ailment, consumer behavior is as follows:-

- ➤ Go to the pharmacist: 45%
- ➤ Go to the doctor: 24%
- Do nothing: 9%

7 BENEFITS AND RISKS OF O.T.C. [29]

7.1 Possible Benefits

- 1. Increased access
- 2. Decreased frequency of visits to physicians, leading to lower healthcare costs
- 3. Improved education of consumers
- 4. Increased autonomy of patients
- 5. Decreased cost to third party players

7.2 Possible Risks

- 1. Inaccurate diagnosis
- 2. Delay in obtaining needed therapy
- 3. Use of suboptimal therapy
- 4. Drug resistance
- 5. Increased costs to patients
- 6. Failure to follow label instructions (Adverse effects, Drug interactions)
- 7. Perceived loss of control by physicians

8 STORAGE AND DISPOSAL [30]

- All drugs (prescription and OTC) should be kept out of reach and sight of children after every use and stored at one wellcontrolled location such as a locked drawer or cabinet. Child-resistant caps must be correctly replaced after every use.
- For proper disposal, the Environmental Protection Agency recommends that drugs be taken out of their containers, mixed with undesirable substances, (e.g., cat litter, used coffee grounds) and put into a disposable container with a lid or into a sealed bag before putting in the trash. Environmentally, it is irresponsible to "flush" OTC medications.

9 CHANGING PRACTICE PATTERNS WILL MAKE A DIFFERENCE [30]

By intensifying patient communications about the correct use of OTC drugs as well as the risks of their incorrect use, physicians can provide a better patient outcome.

- Communicate actively with your patients about the risks of incorrect OTC use. (See sample conversations in Clinical Reference Guide)
- Routinely take a medical history specifically documenting OTC use.

- Provide alternative medication choices if you suspect misuse/abuse
- Review the side effects of medications patients have disclosed during history taking.
- ➤ Teach patients how to read package labeling.
- ➤ Refer patients to Internet educational resources. (See Patient Guide and Patient Education Resources in Clinical Reference)

10 SELECTION CRITERIA OF OTC PRODUCTS

- Single ingredient products are preferred.
- Combination products contain effective doses of all ingredients; others contain therapeutic doses of all ingredients and subtherapeutic doses of others.
- Acetaminophen, for example, is in many cough and cold preparation; a patient unaware of this may take separate doses of analgesic in addition to that contained in the cold preparation, potentially leading to toxicity.
- Select a product that contains a therapeutically effective dose.
- Carefully read the product labeling
- Recommended a generic product if one is available.
- For children, the dose, dosage form and palatability of the product are prime considerations.

11 MISUSE/OVERUSE OF OTC PRODUCTS

- Rebound congestion from the regular use of decongestant nasal sprays for more than 3 days
- Antacid (eg, aluminum hydroxide) may cause constipation and even impaction in elderly people, as well as hypophosphatemia.
- Laxative abuse can result in abdominal cramping and fluid & electrolyte disturbance.
- Insomnia, nervousness and restlessness can result from the use of sympathomimetics or caffeine hidden in many OTC products.

- ➤ Analgesic containing large amount of caffeine may produce rebound headaches.
- Antihistamines may cause sedation or drowsiness especially when taken concurrently with sedative-hypnotics, tranquilizers, alcohol, or central nervous system.
- ➤ Long term use of NSAIDs may increase the risk of heart attack or stroke and intestinal nephritis.
- ➤ OTC products containing aspirin, other salicylates, acetaminophen, ibuprofen, naproxen may increase the risk of hepatotoxicity and gastrointestinal hemorrhage in individuals who consume 3 or more alcoholic drinks daily.

12 CONCLUSIONS

The literature is sparse about OTC medicines" and their review tellingly omits opiate-based OTC analgesics. Pharmacists are also a critical component to realizing the benefits of OTC medications. They assist patients by navigating the many product options and recommending the right medication for an individual's needs. It is important to take medicines correctly, and be careful when giving them to children. More medicine does not necessarily mean better. You should never take OTC medicines longer or in higher doses than the label recommends. If your symptoms don't go away, it's a clear signal that it's time to see your healthcare provider.

Table: 1 Lists of available OTC medicine by Generic name [31]

S. No.	GENERIC NAME	DOSAGE	DOSAGE	INDICATION
1.	D-Alpha Tocopherol	FORM	STRENGTH 300 IU capsule	d-Alpha tocopherol is used for the treatment and prevention of Vitamin E deficiency.
2.	Calcium Ascorbate	Capsule	500 mg	For the treatment and prevention of Vitamin C deficiency
3.	D-Alpha Tocopherol	Capsule	400 IU	Used for the treatment and prevention of Vitamin E deficiency
4.	D-Alpha-Tocopheryl Cid Succinate (Vit E) + Korean Ginseng+ Bee Pollen + Pantothenate + Lecithin	Capsule	150 mg + 100 mg + 150 mg + 30 mg + 50 mg	Used for the treatment and prevention of vitamin deficiencies
5.	Dextramethorphan Hydrobromide + Phenylephrine Hydrochloride + Paracetamol	Capsule	15 mg + 25 mg + 325 mg	For the symptomatic treatment of mild to moderate pain and/or fever
6.	Ferrous Gluconate + Vitamins & Minerals	Capsule		For the treatment of a wide range anemias; iron deficiency anemial anemia during pregnancy, growth, convalescence and senility; megaloblastic and macrocytic heyperchromic anemia; alimentary anemia; prohpylaxis against anemia in blood donors.
7.	Loperamide Hydrochloride	Capsule	2 mg	For the symptomatic control of acute non-specific diarrhea and chronic diarrhea
8.	Multivitamins + Minerals + Deanol + Ginseng Extract	Capsule		Mature & Elderly People - Prophylaxis and treatment of the general symptoms of advancing age such as reduced physical and mental efficiency, fatigue and depressive mood.
9.	Ascorbic Acid + Sodium Ascorbate + Zinc Citrate	Chewable Tablet	20 mg + 90 mg + 5 mg	For the treatment and prevention of Vitamin C and zinc deficiencies
10.	Famotidine + Calcium Carbonate + Magnesium Hydroxide	Chewable Tablet	10 mg + 800 mg + 165 mg	For the treatment and prevention of Vitamin C deficiency
11.	Meclizine Hydrochloride	Chewable Tablet	25 mg	Used in the treatment and prevention of nausea, dizziness and vomiting associated with motion sickness.
12.	Bisacodyl	Enteric- Coated Tablet	5 mg	For the immediate relief of constipation and for bowel evacuation before abdominal radiographic procedures, endoscopy, and surgery

2229-3316				
13.	Calcium + Vitamin D + Minerals	Film- Coated Tablet		For the prevention nad treatment of osteoporosis
14.	Hyoscine-N-Butylbromide + Paracetamol	Film- Coated Tablet	10 mg + 500 mg	For the relief of spastic pain in the smooth muscles of the gastrointestinal, biliary and urogenital tracts
15.	Mefenamic Acid	Film- Coated Tablet	250 mg	For mild to moderate pain in rheumatoid arthritis (including juvenile arthritis), osteoarthritis and relaxed conditions; post operative analgesia; mild to moderate pain; dysmenorrhea and menorrhagia.
16.	Multivitamins	Film- Coated Tablet		For the prevention and treatment of vitamin deficiencies and as nutritional supplement.
17.	Cetirizine Dihydrochloride + Phenylephrine Hydrochloride	Film- Coated Tablet; Syrup	5mg + 10mg; 5mg + 5mg per 5mL	For the relief of clogged nose, sneezing, runny, itchy nose, and itchy watery eyes associated with allergic rhinitis
18.	Extract Cepae + Heparin Sodium + Allantoin	Gel	10 g + 5000 IU + 1 g	Hypertrophic and keloidal scars, movement-restricting and cosmetically disfiguring scars from operations, amputations, burns & accidents; contractures e.g., Dupuytren's contracture & traumatic tendon contracture, cicatricial strictures.
19.	Dequalinium Chloride	Lozenges	250 mg per 5 mL	Is a bisquaternary quinolinium antiseptic, antibactericidal against many Gram-negative and Gram- positive bacteria, and effective against fungi
20.	Dichlorobenzyl Alcohol + Amylmetacresol	Lozenges	1.2 mg + 600 mcg	Used for antiseptic treatment of minor infections of mouth and throat
21.	Mometasone Furoate	Ointment	1 mg per gram (0.1%)	For the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses such as psoriasis and atopic dermatitis.
22.	Hexetidine	Oral Solution	0.10%	To soothe and give temporary relief of minor sore throat
23.	Iron + Vitamin B Complex	Oral Solution		For the treatment and prevention of iron deficiency and nutritional anemias and also for Vitamin B complex deficiency
24.	Ibuprofen	Orally Disintegrat ing Tablet	200 mg	For the management of mild to moderate pain and inflammation and also used to reduce fever
25.	Loratadine	Orally	10 mg	It is uded for the symptomatic

2229-5518				
		Disintegrat ing Tablet		relief of allergy such as hay fever (allergic rhinitis) urticaria, and other skin allergies.
26.	Colecalciferol	Soft Gelatin Capsule	800 IU	For the prevention and treatment of vitamin D deficiency
27.	D-Alpha Tocopheryl + Lecithin	Soft Gelatin Capsule	400 IU + 500 mg; 200 IU + 500 mg	It is used to revitalize body cells, sharpen the brain, improve blood circulation, soothe the nerves, keep muscle healthy and strengthen the heart.
28.	Guaifenesin	Soft Gelatin Capsule	200 mg	For the unproductive cough accompanying various respiratory tract infection and realated disorder
29.	Multivitamins + Minerals + Deanol + Royal Jelly + Korea Panax Ginseng	Soft Gelatin Capsule		As a supplement during convalescence after illness to achieve balance intake of vitamins by individuals with increase needs or marginal deficiency.
30.	Chamomile Extract + Methyl Salicylate + Pepermint Oil + Sage Oil	Spray Solution	370.5 mg + 1 mg + 18.5 mg + 6 mg per mL	For inflammatory infections of the buccal and pharyngeal cavity; parodontosis; acute gingivitis; pain after tooth extraction and during second dentition; mucosal irritation caused by dental plates; tonsillary angina; canker soers and bad breath
31.	Fusidic Acid	Suspension ; Cream	50 mg per mL; 2%	Used for the treatment of skin infection cause by staphylococci, streptococci, Propionibacterium acnes, Corynebacterium minutissimum and other Fudicin sensitive organisms
32.	Brompheniramine Maleate + Phenylephrine Hydrochloride	Syrup	2 mg + 5 mg per 5 mL	For the symptomatic relief of nasal congestion, relief of cough and colds and allergic conditions
33.	Butamirate Citrate	Syrup	7.5 mg per 5 mL	Cough suppressant used in non- productive cough
34.	Cetirizine (As Dihydrochloride)	Syrup	1 mg per mL	For the symptomatic relief of allergic conditions
35.	Dextromethorphan Hydrobromide	Syrup	10 mg per 5 mL	For chronic, nonproductive irritative cough
36.	Dextromethorphan Hydrobromide + Guaifenesin	Syrup	15 mg + 100 mg per 5 mL	For the relief of cough associated with common colds, influenza, allergy, and other respiratory infections, particularly for dry, unproductive cough
37.	Diphenhydramin HCl + Phenylpropanolamine HCl	Syrup	12.5 mg + 12.5mg per 5 mL	For the relief of symptoms associated with the common cold, flu, allergic rhinitis, acute laryngitis, acute and chronic

2229-5518				
				pharyngitis such as cough, nasal congestion, sneezing, runny nose and itchy eyes
38.	Carbocisteine	Syrup; Oral Drops	100 mg per 5mL; 50 mg per mL	For the treatment of acute to chronic disorders of the upper and lower respiratory tract
39.	Ascorbic Acid	Syrup; Sugar- Coated Tablet	100 mg per 5 mL; 500 mg	For the treatment and prevention of Vitamin C deficiency
40.	Ambroxol Hydrochloride	Tablet	30 mg	For the treatment of respiratory diseases associated with productive cough
41.	Ascorbic Acid + Sodium Ascorbate	Tablet	200 mg + 366 mg	For the treatment and prevention of Vitamin C deficiency
42.	Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride + Paracetamol	Tablet	2 mg + 25 mg + 500 mg	For the symptomatic treatment of mild to moderate pain and/or fever
43.	Ferrous Sulfate	Tablet	325 mg	For the symptomatic treatment of mild to moderate pain and/or fever
44.	Glutamic Acid + Dicalcium Phosphate + Thiamine Hydrocloride + Cyanocobalamin	Tablet	325 mg + 200 mg + 5 mg + 10 mcg	For the prevention and treatment of vitamin B deficiencies.
45.	Hyoscine-N-Butylbromide	Tablet	10 mg	Used for the symptomatic relief of gastro - intestianal or gastro-urinary disorders characterized by smooth muscle spasm
46.	Ibuprofen + Paracetamol	Tablet	325 mg + 200 mg	For the relief of mild to moderate pain and inflammation in dysmenorrhea, headache, postoperative pain, dental pain, musculoskeletal and joint disorder and the reduction of fever.
47.	Multivitamins + Minerals	Tablet		For the prevention and treatment of vitamins and minerals deficiencies
48.	Multivitamins + Minerals + Amino Acids	Tablet		For the prevention and treatment of vitamin deficiency states.
49.	Benzoyl Peroxide	Topical Gel	5%, 10%	For the treatment of acne vulgaris
50.	Clotrimazole	Topical Solution	10 mg per mL (1%)	It is used topically in superficial candidiasis and in skin infections pityriasis versicolor and dermatophytosis. Clotrimazole is also indicated in the treatment of vulvovaginal candidiasis

Table: 2 Lists of available OTC medicine by Trade Name [32, 33, 34]

S. NO.	OTC CATEGORY	INGREDIENT AND ADULT DOSAGE	TRADE NAME
1.		Cimetidine,200mg once or twice daily	Tagamet HB
	Acid reducers (H2 antagonists)	Famotidine, 10-20 mg once or twice daily	Pepcid AC
		Ranitidine 75 - 150mg once or twice daily	Zantac 75, Zantac 150
2.	Acid reducers (proton pump inhibitors)	Omeprazol, magnesium 20.6mg once daily for 14 days	Prilosec
3.	antacids	Magnesium hydroxide and aluminum hydroxide alone or in combination	Amphogel, milk of magnesia, various generic
4.	Acne preparation	Benzoyl peroxide 5%, 10%	Clearasil, various generic
5.	Analgesics and antipyretics	Acetaminophen, 325-650mg every 4-6 hours; 650-1300mg (extended release) every 8 hours. Aspirin 325-650mg every 4-6 hours Ibuprofen, 200-400mg every 4-6 hours (not to exceed 1200mg daily) Ketoprofen, 125 mg every 4-6 hours. Naproxen sodium, 220mg every 8-12 hours Chlorpheniramine,4mg every 4-6	Panadol, Tynenol, Tylenol 8Hour, various generic Bayer Asprin, Ecotrin, Bufferin, various generic Advil, Motrin, various generic Orudis KT Aleve, various generic Chlor-trimeton allergy 4
6.	Allergic and cold preparations	hours,8-12mg(extended-release) every 8-12 hours Diphenhydramine, 25-50mg every 4-6 hours Loratadine (10mg) with pseudoephedrine (240mg)every 24 hours	hour, various generic Benadryl allergy, various generic Claritin-D 24 hour
7.	Anthelmintics (pinworm	Pyrantel pamoate, 11mg/kg	Antiminth, Pin-x.
8.	infection) Antidiarrheal agents	(maximum:1g) Bismuth subsalicylate, 524mg every 30-60minutes as needed up to 8 doses daily Lopramide, 4mg initially, then 2mg after each loose stool, not to exceed 8mg daily	Kaopactate,Pepto-Bismol, various generic Imodium A-D, various generic
9.	Antifungal (topical)	Butenafine,1% (cream) Clotrimazole, 1% (cream) Miconazole, 2% (cream, powder, solution)	Lotrimin Ultra Lotrimin AF cream Cruex, Lotrimin AF powder
10.	Antifungal (Vaginal)	Butoconazole, 2% cream, one applicatorful intravaginally at bedtime for 3 consecutive days.	Mycelex-3

		Clotrimazole, 1%, 2% (cream),	Gyne- Lotrimin, Mycelex-
		100mg, 200mg suppositories.	7, various generic
11. Anti-inflammatory (Topical)		Hydrocortisone, 0.5% & 1%	Cortisone-5 & cortozone-
		(cream, lotion, spray, ointment)	10.
12.	Antiseborrheal agents	Ketoconazole 1% shampoo, apply	Nizoral A-D
		every 3-4days	
		Selenium sulfide, 1% shampoo,	Head & Shoulders
		apply one or twice weekly	
13.	Antitussive	Codeine, 10-20mg every 4-6 hours	Guiatuss AC
14.	Decongestants (Topical)	Oxymetazoline, 0.05% nasal solution	afrin
15.		Xylometazoline 0.05%,0.1%	otrivin
16.	Decongestants (systemic)	Phenylephrine	
17.	Emergency contraceptive	Levvonorgestrol, 0.7mg tablet	Plan B
		taken as soon as possible but no	
		later than 72 hours after	
		unprocted sex	
18.	Expectorants	Guaifenesine,100-400mg every 4	glytuss
		hours	
19.	Hair growth stimulants	Manoxidil,2%,5%solution apply	Rogaine
		1ml to affected areas of scalp	
		twice daily	
20.	Laxatives	Bulk formers: Psyllium & Methyl	Citrucel
		cellulose	
		Stool softeners: Docusate sodium,	Colace
		50-500mg daily.	
21.	Pedicullcides (Head lice)	Permethrin 1%	Nix
22.	Sleep aids	Diphenhydramine, 25-50mg at	compoz
		bedtime	
		Doxylamine, 25mg at bedtime	unisom
23.	Smoking cessation aids	Nicotine (transdermal system)	Nicoderm CQ, Nicotrol.

REFERENCES

- Consumer Healthcare Products
 Association. The Value of OTC Medicine to the United States, January 2012. Retrieved from http://www.chpa.org/ValueofOTCMeds20 12.aspx.
- 2. World Health Organization Regional Office for Southeast Asia. "Self-care in the Context of Primary Health Care," 7-9 January 2009.
- Consumer Healthcare Products
 Association. Statistics on OTC Use.
 http://www.chpa.org/MarketStats.aspx#access.
- 4. Bessell, T. L., Anderson, J. N., Silagy, C. A., Sansom, L. N., & Hiller, J. E. (2003).

- Surfing, self-medicating and safety: Buying non-prescription and complementary medicines via the Internet. *Quality & Safety in Health Care*, 12(2), 88–92.
- 5. Bissell, P., Ward, P. R., & Noyce, P. R. (2001). The dependent consumer: Reflections on accounts of the risks of non-prescription medicines. *Health*, 5(1), 5–30.
- 6. Hughes, L., Whittlesea, C., & Luscombe, D. (2002). Patients' knowledge and perceptions of the side-effects of OTC medication. *Journal of Clinical Pharmacy Therapeutics*, 27, 243–248.
- Raynor, D., Blenkinsopp, A., Knapp, P., Grime, J., Nicolson, D., Pollock, K., Dorer, G., Gilbody, S., Dickinson, D., Maule, A. J., & Spoor, P. (2007). A systematic review of quantitative and qualitative research on

- the role and effectiveness of written information available to patients about individual medicines. *Health Technology Assessment*, 11(5), 1–160.
- 8. Lessenger, J. E., & Feinberg, S. D. (2008). Abuse of prescription and over-thecounter medications. *Journal of the American Board of Family Medicine*, 21(1), 45–54.
- 9. Reay, G. (2009). An inquiry into physical dependence and addiction to prescription and over-the-counter medication. London: All-Party Parliamentary Drugs Misuse Group.
- Frei, M. Y., Nielsen, S., Dobbin, M., & Tobin, C. L. (2010). Serious morbidity associated with misuse of over -the-counter codeine-ibuprofen analgesics: A series of 27 cases. *Medical Journal of Australia*, 193(5), 294–296.
- 11. Over-the-Counter Medicines: What's Right for You?. Fda.gov (2009-04-30). Retrieved on 2012-07-04.
- 12. The New Over-the-Counter Medicine Label: Take a Look. Fda. gov (2012-04-27). Retrieved on 2012-07-04.
- FDA Approves Plan B One-Step Emergency Contraceptive; Lowers Age for Obtaining Two- Dose Plan B Emergency Contraceptive without a Prescription. Fda.gov. Retrieved on 2012-07-04.
- FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older.
 Fda.gov (2009-04-30). Retrieved on 2012-07-04.
- 15. D&c
- http://www.yourhealthathand.org/images/ uploads/CHPA_OTC_Trust_Survey_White _Paper.pdf.
- 17. American Pharmacist's Association (APhA). (July 1, 2013). Counseling Patients on Choosing and using OTCs. Retrieved from http://www.pharmacist.com/counseling-

patients-choosing-and-using-otcs.

- 18. World Health Organization. (2004). The World Medicines Situation. Retrieved from http://apps.who.int/medicinedocs/pdf/s616 0e/s6160e.pdf.
- Sirima SB, Konate A, Tiono AB Convelbo N, Cousens S, Pagnoni F. Early treatment of childhood fevers with pre-packaged anti-malarial drugs in the home reduced

- malaria morbidity in Burkina Faso. Trop Med Health 2003 Feb; 8(2): 133-9.
- Hopkins H, Talisuna A, Whitty CJ, Staedke SG. Impact of home based management of malaria in Africa: a systematic review. Malar J. 2007 Oct 8;6:134.
- 21. World Self-Medication Library. Switch:
 Prescription to Nonprescription medicines
 Switch. WSMI 2009. Retrieved from
 http://www.wsmi.org/pdf/wsmi_switchbro
 chure.pdf.
- 22. 15 Harrington, P. & Shepherd, M.D. Analysis of the Movement of Prescription Drugs to Over the-Counter Status. *Journal* of Managed Care Pharmacy. November/December 2002, 8(6). Retrieved from http://amcp.org/WorkArea/DownloadAsse t.aspx?id=6696.
- 23. C.P. de Joncheere et al. (Eds.). Drugs and Money: Prices, affordability and costcontainment. 7th Ed. 2003, Amsterdam. World Health Organization. Retrieved from http://apps.who.int/medicinedocs/ pdf/s4912e/s4912e.pdf.
- 24. Keeler, T.E, Hu, T.W., Keith, A., Manning, R., Marciniak, M.D., Ong, M., & Sung, H.Y. The benefits of switching smoking cessation drugs to over-the-counter status. HealthEcon. 2002 Jul;11(5):389-402. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12112489.
- 25. Alexander, GC; Mohajir N, Meltzer DO (2005). "Consumers' perceptions about risk of and access to nonprescription medications". Journal of theAmerican Pharmacists Association 45 (3): 363–370. doi:10.1331/1544345054003868. PMID 15991758.
- 26. FDA Approves Plan B One-Step Emergency Contraceptive; Lowers Age for Obtaining Two- Dose Plan B Emergency Contraceptive without a Prescription. Fda.gov. Retrieved on 2012-07-04.
- 27. FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older. Fda.gov (2009-04-30). Retrieved on 2012-07-04.
- 28. Alexander, GC; Mohajir N, Meltzer DO (2005). "Consumers' perceptions about risk of and access to nonprescription

- medications". Journal of the American Pharmacists Association 45 (3): 363–370. doi:10.1331/1544345054003868. PMID 15991758.
- 29. Erin E.Baca, Juan Holguin Jr. and Andreas W. Stratemeyer, "Direct to consumer advertising and young consumers; building brand value", The Journal of Consumer Marketing (2005); 379-387.
- 30. Over-the-counter medications: use in general and special populations, therapeutic errors, misuse, storage and disposal. A Resource from the American College of Preventive Medicine.

- 31. Food and drug administration over the counter drug indications. Republic of the Philippines.
- 32. US Food and Drug Administration website. FDA Approved Drug Products: http://www.accessdata.fda.gov/scripts/cde r/drugsatfda/index.cfm.
- 33. Consumer Healthcare Products
 Association website:
 http://www.chpa.org/.
- 34. Handbook of Nonprescription Drugs, 17th ed. American Pharmacists Association, 2011.

IJSER