Topic: OTC Medication
Subject: Dispensing and Community Pharmacy
Class F.Y. B.Pharmacy (A &B)
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Mapping of TLO with Course Outcome (COs)

S.No.	Topic Learning Outcome	COs	BL
1.	Explain concept of OTC medication	CO2	L2

OTC MEDICATIONS

OTC DRUGS

OTC drugs are the medicines that are legally allowed to be sold 'Over the counter' by a community pharmacist without formal prescription.

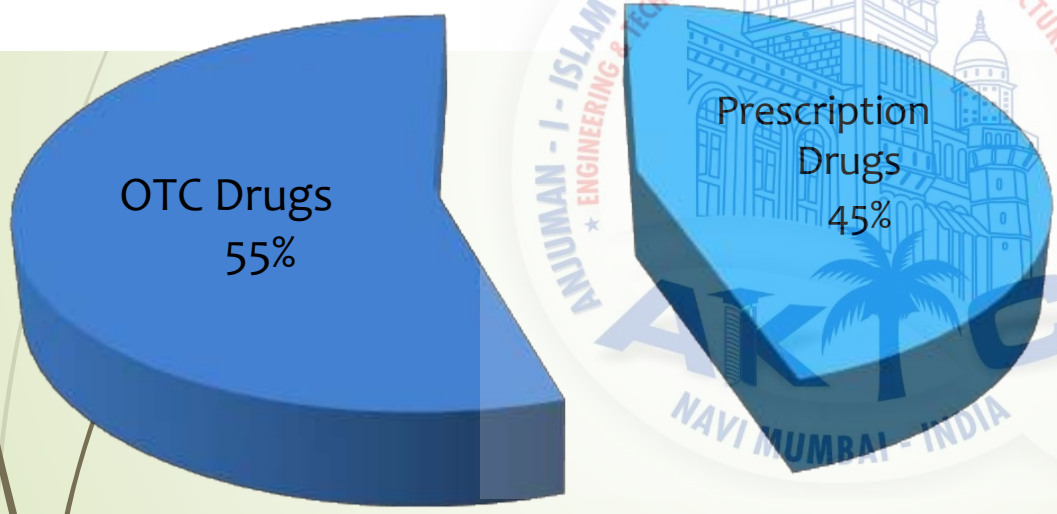
- It is also called prescription de controlled drugs.
- These drugs are the non prescription or over-the-counter drugs.
- These have little significant pharmacological activity and therefore the physician need not to be very much concerned about their use by the patients themselves.
- It is used primarily for symptomatic relief and not as substitutes for prescription drugs.

SIGNIFICANCE

- Comparatively cheaper
- Chemist himself may prescribe OTC
- consumers are able to
  - Self diagnose
  - Self treat
  - Self manage
- OTC considered as time saving medications. Some patients do not want to spend much time at physicians clinic.
- Lesser number of side effect compared to prescription medications.

MARKET ANALYSIS

Drugs Used by Indians



"Over-the-counter drug products account for 55 percent of drugs used by Indians."

Prescription drugs	OTC drugs
H or X- labelled as ''Warning- Schedule H Drug''. ''Warning- To be sold by retail on the prescription of a registered medical practitioner only''.	Schedule K drug of drug and cosmetics act
Safety window -narrow	Wider safety window. They are safe only after following proper instructions
Accuracy and correctness of the dosage is required for effectiveness and safety	Dose with frequency of administration is permitted within limits of advisory labels.
Physician will be held responsible	pharmacist
Direction to use is usually- use as directed by physician	Detailed information about dose, dosing schedule, precautions and warning is printed on label as well as product information leaflet.

Merits of OTC medications

- OTC medications are considered to be safe and effective in minor ailments.
- It is more convenient for patient to procure.
- No need to visit physician and in that turn, patient can save consultation time and charges.
- OTC medicines are comparatively cheaper than the prescription drugs.
- Pharmacist can dispense these medicines without prescription, taking moral responsibility of therapy and its outcome, which helps to improve patient-pharmacists relations.

Demerits of OTC medication

- OTC medicines can promote the practice of self medication, which may be dangerous. For example: gastro-intestinal bleeding on frequent use of pain killer (NSAIDS)
- Community Pharmacist dispensing OTC drugs upon demand by patient/consumer do not have sufficient knowledge and attitude to communicate with them regarding the precautions to be taken.
- Unregulated advertisement of OTC medicines can promote irrational use of OTC drugs. For example, frequent use of Dispirin for headache, addictive use of Dulcolax.

TYPES OF OTC MEDICATIONS

* ANALGESICS
* ANTIBIOTICS
* COUGH SUPPRESSENTS
* ANTI ACNE DRUGS
* NSAIDS
* ANTISEPTICS
* DECONGESTANTS
* ANTACIDS
* ANTIFUNGALS ANTI
* HISTAMINES
* SMOKING CESSATION DRUGS

Topical Antibiotic

Topical Antibiotics are medicines applied to the skin to kill bacteria. They are used to treat or prevent infections that occur on minor cuts, scrapes, and burns due to presence of bacteria.

Cough Suppressants

Cough Suppressants are medicines that prevent or stop coughing. A cough suppressant is used for treating dry coughs (antitussives). It helps to suppress the body's urge to cough. Cough suppressants are different from cough expectorants. Cough expectorants help in treating productive coughs (coughs that produce phlegm).

Anti Acne Drugs

Anti-acne drugs are medicines are used in the treatment of various acne problems like pimples, whiteheads, blackheads, and other serious forms of acne.

Nonsteroidal Anti-Inflammatory Drugs

Nonsteroidal anti-inflammatory drugs are medicines that are used to treat inflammation, mild to moderate pain, and fever. They are basically drugs with analgesic and antipyretic effects and with higher doses, they have anti-inflammatory effects.

Antiseptics Medicine

Antiseptics in the form of lotions, creams, ointment are medicines that slow or stop the growth of germs and help prevent infections in cuts, scrapes, and burns.

Analgesics Drugs

Analgesics are medicines that relieve pain.

Decongestant

Decongestants are the drugs or medicines used to relieve nasal congestion, which in common terms, refer to stuffy nose.

Antacids

Antacids are the medicines or drugs that neutralizes the stomach acids.

Antihistamines

Anti- Histamines are medicines that relieve or prevent the symptoms of allergy like Hay Fever, itchy eyes, sneezing, runny nose and other kinds of allergy .

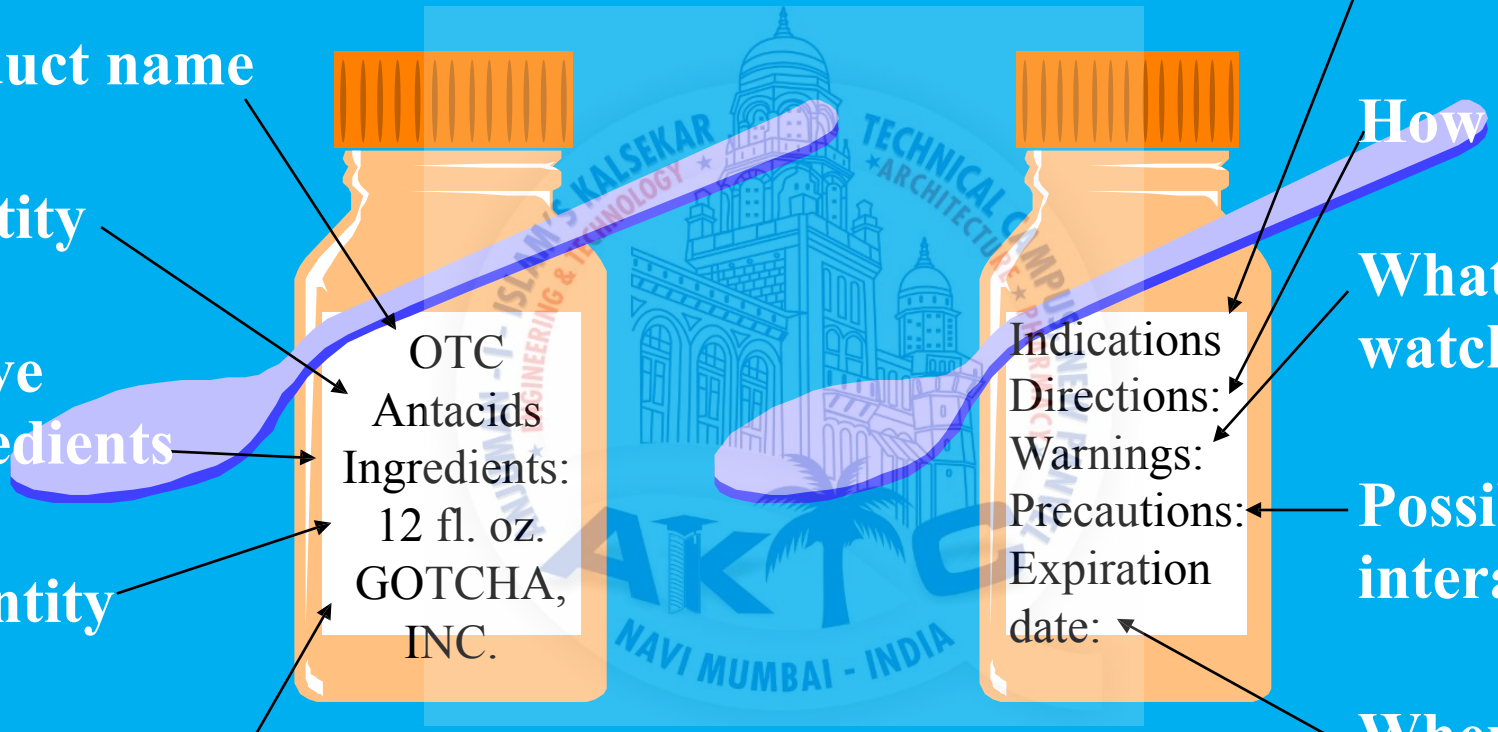
Anti Fungal Drug

Anti-Fungal Drugs are used to treat infections caused by a fungus.

Smoking Cessation Drug

Smoking-cessation Drugs are medicines that are used to help people stop smoking cigarettes or using other forms of tobacco .

Label information controlled by the FDA



RULES FOR THE PROPER USE OF OTC DRUGS

* Always know what you are taking.
* Know the effects.
* Read the warnings and cautions.
* Don't use anything for more than 1 to 2 wks.
* Be particularly cautious if also taking prescription drugs.
* If you have questions, ask a pharmacist.
* If you don't need it, don't use it!

SPECIAL PATIENT GROUPS

Many patient groups may be particularly susceptible to adverse events that are caused by OTC products.

They include:

- Children
- Women who are pregnant or breast feeding
- Geriatric patients
- People taking prescription drugs & people having health problems

OTC Medications Are Safe But Not Risk-Free

As with all medications, there can be risks with use

The risks of OTC use include:

- Delay in seeking medical advice for a serious illness.
- Risk of drug-drug/herbal/dietary supplement
- interactions.
- Risk of adverse events.
- Potential for dependence, misuse and abuse.

MISUSE AND ABUSE OF OTC DRUGS

- Physical dependence
- Psychological dependence
- Nonprescription products that can be severely habit- forming: decongestants, laxatives, antihistamines, sleep aids, antacids and ephedrine.
- Only 16% reads the entire product label.
- If they read them they do not follow the directions on the label.

Abuse is most common in adolescents aged 10-17 years.

Adolescents are 18% times more likely to dies from an OTC overdose than from a illicit drug dose overdose.

OTC PRODUCTS LIABLE TO MISUSE

Product type	examples
Solvents	methylated and surgical spirit
Propellants	pain relieving sprays
Chemicals	citric acid
Opioids	codeine, morphine
Laxatives	senna

Overdosing has occurred with non prescription medicines, particularly those that contain paracetamol. Adverse reactions can also occur but rare. Pharmacist should therefore ensure that advice and information are available on the safe and effective use of medicines.

In what way the OTC drugs can be Harmful.

- OTC drugs can change the effect of prescription medications.
- OTC drugs can mask symptoms of disease.
- OTC drugs can lead to overdose.
- If misused even common over-the-counter drugs, such as aspirin, vitamins, or cold remedies can be harmful.

RATIONAL USE OF OTC DRUGS

ANALGESICS

Pain relief medicines (also known as "analgesics" and "painkillers") are regulated by the Food and Drug Administration (FDA).

Some analgesics, including opioid analgesics, act on the body's peripheral and central nervous systems to block or decrease sensitivity to pain. Others act by inhibiting the formation of certain chemicals in the body.

These relieve the minor aches and pains associated with conditions such as headaches, fever, colds, flu, arthritis, toothaches, and menstrual cramps.

There are basically two types of OTC pain relievers:

- acetaminophen
- non- steroidal anti- inflammatory drugs (NSAIDs).

* Acetaminophen is an active ingredient found in more than 600 OTC and prescription medicines, including pain relievers, cough suppressants, and cold medications.

* NSAIDs are common medications used to relieve fever and minor aches and pains. They include aspirin, naproxen, and ibuprofen, as well as many medicines taken for colds, sinus pressure, and allergies. They act by inhibiting an enzyme that helps make a specific chemicals.

Use as Directed

Pain medications are safe and effective when used as directed. However, misuse of these products can be extremely harmful and even deadly.

- Consumers who take pain relief medications must follow their health care professional's instructions carefully. If a measuring tool is provided with your medicine, use it as directed.
- Do not change the dose of your pain relief medication without talking to your doctor first.
- Also, pain medications should never be shared with anyone else. Only your health care professional can decide if a prescription pain medication is safe for someone.

Key points to remember.

With acetaminophen:

- Taking a higher dose than recommended will not provide more relief and can be dangerous.
- Too much can lead to liver damage and death.
  Risk for liver damage may be increased in people who drink three or more alcoholic beverages a day while using acetaminophen-containing medicines.
- Be cautious when giving acetaminophen to children. Infant drop medications can be significantly stronger than regular children's medications. Read and follow the directions on the label every time you use a medicine. Be sure that your infant is getting the infants' pain formula and your older child is getting the children's pain formula.

With NSAIDs:

- Too much can cause stomach bleeding. This risk increases in people who are over 60 years of age, are taking prescription blood thinners, are taking steroids, have a history of stomach bleeding or ulcers, and/or have other bleeding problems.
- Use of NSAIDs can also cause kidney damage. This risk may increase in people who are over 60 years of age, are taking a diuretic (a drug that increases the excretion of urine), have high blood pressure, heart disease, or pre-existing kidney disease.

With opioids:

- Use of opioids can lead to drowsiness. Do not drive or use any machinery that may injure you, especially when you first start the medication.
- The dose of an opioid pain medication that is safe for you could be high enough to cause an overdose and death in someone else, especially children.

Know the Active Ingredients

A specific area of concern with OTC pain medicines is when products sold for different uses have the same active ingredient. A cold and cough remedy may have the same active ingredient as a headache remedy or a prescription pain reliever.

- To minimize the risks of an accidental overdose, consumers should avoid taking multiple medications with the same active ingredient at the same time.
- All OTC medicines must have all of their active ingredients listed on the package. For prescription drugs, the active ingredients are listed on the container label.
- Talk with your pharmacist or another health care professional if you have questions about using OTC medicines, and especially before using them in combination with dietary supplements or other OTC or prescription medicines.

Misuse and Abuse

Misuse and abuse of pain medications can be extremely dangerous. This is especially so in regard to opioids. These medications should be stored in a place where they cannot be stolen.

According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction.

But the abuse of opioids is a significant public safety concern. Abusers ingest these drugs orally, and also crush the pills in order to snort or inject them.

Commonly abused opioid pain medicines include prescription drugs such as codeine, and the brand-name products Oxycontin (oxycodone), Vicodin (hydrocodone with acetaminophen), and Demerol(meperidine).

Addiction is just one serious danger of opioid abuse. A number of overdose deaths have resulted from snorting and injecting opioids, particularly the drug OxyContin, which was designed to be a slow-release formulation.

3 Key Steps to Use Opioids Safely:

- Keep your doctor informed. Inform your health care professional about any past history of substance abuse. All patients treated with opioids for pain require careful monitoring by their health care professional for signs of abuse and addiction, and to determine when these analgesics are no longer needed.

- Follow directions carefully. Opioids are associated with significant side effects, including drowsiness, constipation, and depressed breathing depending on the amount taken. Taking too much could cause severe respiratory depression or death. Do not crush or break pills. This can alter the rate at which the medication is absorbed and lead to overdose and death.

- Reduce the risk of drug interactions. Don't mix opioids with alcohol,antihistamines, barbiturates, or benzodiazepines. All of these substances slow breathing and their combined effects could lead to life-threatening respiratory depression.

COUGH SUPPRESSENTS

The role of cough medicine is to ease symptoms while your body heals.

OTC cough medicines are only three basic types:

* Expectorants help thin mucus, making it easier to cough up.Main ingredient is the guaifenesin.

* Suppressants help cut the number of times you cough. The active ingredient listed is usually dextromethorphan (DM). Other cough suppressants include camphor, eucalyptus oil, and menthol.

* Combination cough products have more than one active ingredient. They have both guaifenesin and dextromethorphan. Cough medicines may also contain ingredients to help coat and soothe the throat.

* Combination products may have medicines to ease other symptoms, that may include decongestants for stuffy nose, antihistamines for allergies or a runny nose, or painkillers. Choose a medicine that matches your symptoms.

* Cough drops can also help relieve a cough and may ease a sore throat.

* Cough suppressants containing opioid should be taken with extreme caution. The main ingredient of opioid cough suppressants are dextromethorphan.

How to Use Cough Medicine Safely

- Look at the ingredients.
  Check the label. Is it a suppressant or an expectorant? Is it both? Make sure you're getting what you need.

- Don't use medicine for more than 7 days.

- Always measure the correct dose.
  Because even safe medicines in high doses can be very dangerous. High doses of cough medicine can cause serious problems, including brain damage, seizure, or death.

- Be careful with combination medicines. Many OTC cough medicines have multiple ingredients -- expectorants and suppressants along with decongestants, antihistamines, or painkillers. Select products with only the medicines that treat your symptoms. If your symptom is only a cough, for instance, you don't need a decongestant or painkiller. If you need to treat multiple symptoms, check other medicines you take to see if they contain the same ingredients. Don't take two medicines that have the same ingredients. If you have any questions, ask your pharmacist or doctor.

- Keep away from young children. Make sure to choose the right medicine based on your child's age. Don't give cough and cold medicine to children under age 4. For kids 4 to 6, ask your doctor first. And always make sure to follow the dosing directions on the label.

- Consider doing nothing. Waiting out a cough is the simplest option. Remember that most coughs don't need treatment. You don't have to take any medicine. Give your body a week and your cough will probably go away on its own. If it doesn't, see your doctor.

- Read the label. After you choose the right medicine for you, read the label carefully, so you understand how to take it, common side effects, and any warnings you need to be aware of.

NSAIDS

* NSAIDs are nonsteroidal anti-inflammatory drugs.

NSAIDs are one of two major types of OTC pain relievers. The other is acetaminophen (Tylenol).

A few different types of NSAIDs are available over the counter:

* Aspirin (Bayer, Bufferin, Excedrin)
* Ibuprofen (Advil, Motrin IB)
* Naproxen (Aleve)

NSAIDs are used to reduce fever and relieve mild aches and pains. They can be used for everything from a mild toothache or headache to cramps. Many people also use NSAIDs to relieve the pain of arthritis or to treat the aches and pains of the common cold and flu.

NSAIDs work by blocking enzymes in the body that help make chemicals that signal pain. When these enzymes are blocked, you feel less pain

SPECIAL PATIENT GROUPS

Talk with your doctor before taking any NSAID if you: Are

- over age 60
- Are pregnant or nursing
- Have three or more drinks of alcohol every day
- Have bleeding problems liver or kidney disease
- Have heart disease
- Have a medicine to thin the blood, such as warfarin
- Ta k ea medicine for high blood pressure (Coumadin)
- Take

- Children and teenagers who are recovering from a viral infection such as the flu or chickenpox should not take aspirin. It has been linked to Reye's syndrome, a serious but rare condition that can result in brain, kidney, and liver damage.

- Naproxen sodium is not recommended for children under 2.

- Ibuprofen is considered safe for children 6 months and older in the right dose

To reduce your risk of problems with NSAIDs, try these tips:

- Don't drink alcohol. Drinking alcohol while you're taking an NSAID increases your risk of bleeding.
- Take NSAIDs with food and water.
- If you have a history of stomach problems, ask your doctor about taking a drug that blocks stomach acid with the NSAID.

When choosing pain relief medication, it's most important to take the lowest dose that works for you and to take it as directed.

And if your pain continues for more than a 10 days or isn't controlled by the OTC NSAID, it's a good idea to talk with your doctor.

COUNSELING

OTC COUNSELING QUESTIONS

Counseling patients about self-care and nonprescription drugs is not the same and cannot follow the same procedure as for prescription drugs. That is why OTC counseling requires much more exploratory open or close- ended questions on the part of the pharmacist which are especially useful to clarify information gathered about the patient's condition. It allows gathering the most abundant amount of information.

These questions usually start with who, what, how, why or where. For example:

* "Which of the prescription medications do you take on regular basis?"
* "Which of the nonprescription and herbal medications do you use?"
* "What types of conditions do you routinely see your doctor for?"

Some other questions are also possible:

* "Have you ever experienced any side effects after taking the OTC medication?"
* "Have you taken this OTC medication before?"

PATIENT COUNSELING

* Step I

Every pharmacist should begin the OTC counseling session by introducing himself/herself by name which identifies him/her as the pharmacist. He/she should try to relax the patient by beginning the session with a friendly smile and a handshake. The pharmacist should also explain that he/she can provide assistance with OTC product selection and explain how to use such medication.

* Step 2

In order to elicit key information the pharmacist should first and foremost t obtain relevant information about patient's demographic (e.g. sex, age, pregna nursing, weight, allergies, social history etc), disease (e.g. history of presen illness, current symptoms, course of illness, past history, other underlying medi conditions) and drug (e.g. current medication, medication tak history etc.) Moreover, by using suitable verbal and written c techniques, the pharmacist should inform, educate, and counsel patients abou the following:

- Drug name (generic and/or brand name)
- Route, dosage form, dosage and administration schedule;
- Special directions for preparation and administration as well as precautions to be taken during the process;
- Techniques for self-monitoring of drug therapy;
- Storage;
- Potential drug-drug or drug-food interactions or other therapeutic contraindications ; and
- Accordingly other Information "peculiar to the specific patient or drug etc.

In addition, it is of vital importance to demonstrate to patient's- how to use medications in various forms such as inhalers, patches, drops, ointments, lozenges, gargles etc.

And

Ask them to demonstrate making sure that patients understand which route of administration should be used thus ensuring that patients have all the necessary instructions in writing and that they understand how to schedule their medications in accordance with meals and other medications.

Reference

- Dr. Atmaram Pawa, Bijoy Kumar Panda; Community pharmacy; Nirali Prakashan.

Review Questions

S.N.	Questions	Co and BL
1	Give any four examples of OTC products.	CO2. L2
2	What are OTC medications? Give 2 examples.	CO2. L2
3	Discuss OTC medication in brief.	CO2. L2