



## MONITORING THE SAFETY ASPECTS OF OVER THE COUNTER MEDICATIONS

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### ABSTRACT

OTC medication is short for over the counter drugs. These medicines have become popular as they are available without a prescription from the doctor. These are medicaments that are usually used to relieve pain and to treat various symptoms of cold. Most of the over-the-counter users believe that these medications are safer and are devoid of unwanted side effects. But their use may become fatal sometimes when they are administered without knowing the prescription pattern, that is, when they are used without properly reading the directions on the label. More over, the consumers are not aware of the safety of these drugs and its frequent use may result in various adverse effects. It is the part of the patient to read out the label packaging instructions for OTC medications to know how much one should take, the possible side effects that may encounter and the various conditions that can result in poor choice of the drug. Various other aspects such as the recommended dose, contraindications and drug interactions should be considered before taking OTC drugs. Pharmacists and drug companies will have an increasingly important role in giving information and advice to the patients. This review highlights the safety aspects of OTC drugs. It summarizes the safety measures that should be taken into consideration when used among different age groups.

**KEYWORDS** – Drug interaction, OTC medication, prescription pattern, Recommended dose, contraindications, Adverse effects

### INTRODUCTION

Over the counter medications are those which one can buy without a doctor's prescription<sup>1-2</sup>. It has been found that many prescription medications are being switched on to OTC status<sup>3</sup>. These medicines have a low risk of side effects when they are used by a normal healthy person. Over the counter medications are safer and effective only when they are used accordingly following the instruction patterns. It should be used with precautions for different age groups such as children, pregnant women and older people. As many people rely on over the counter medicines to treat various symptoms they should be aware of the safety of these medications. Safety is a major concern and also possible delays in the diagnosis of serious condition.

#### How To Read An OTC Drug Label

1 A prescription is not needed to buy OTC medicine. But like prescription drugs, OTC medicines can also cause unwanted and sometimes dangerous side effects. Before one buys an OTC medicine, it's important to read and thoroughly understand the information on the drug label. Use the following as a guide. If you have questions about a medicine, ask your pharmacist or family doctor.

2 **Active Ingredient.** The active ingredient is the chemical compound in the medicine that works to relieve your symptoms. It is always the first item on the label. There may be more than one active ingredient in a product. The label will clearly show this.

3 **Uses.** This section lists the symptoms the medicine is meant to treat. The U.S. Food and Drug Administration (FDA) must approve these uses. Uses are sometimes referred to as "indications."

4 **Warnings.** This safety information will tell you what other medicines, foods or situations (such as driving) are to be avoided while taking this medicine.

5 **Directions.** Information about how much medicine you should take and how often you should take it will be listed here.

6 **Inactive Ingredients.** An inactive ingredient is a chemical compound in the medicine that isn't meant to treat a

symptom. Inactive ingredients can include preservatives, binding agents and food coloring. This is especially important for people who have allergies to food coloring or other chemicals<sup>4-6</sup>.

#### Are Children's Oral Cough Cold OTC Medications Safe?

Yes. Children's OTC oral cough and cold medications are safe and effective when given as directed. Although problems with these medicines are very rare and mostly related to incorrect dosage, it is necessary for the parents to follow the label directions on the drug facts label. The following tips will show when and when not to give OTC oral cough and cold medicines to a child.

- Always read and follow medicine labels exactly and use the measuring device that comes with the medicine.
- Do not give a medicine, only intended for the adults, to a child.
- Only give the medicine that treats the child's specific symptoms.
- Never give two medicines at the same time that contain the same active ingredient. It can result in increase in dose than recommended.
- Do not use oral cough and cold medicines for children under age four.
- Never use an OTC medicine to sedate or make a child sleepy.
- Never give aspirin containing products to a child for cold or flu symptoms unless told to do so by a doctor.
- Keep all the medicines out of child's reach and sight.
- Talk to a doctor, pharmacist or other health care provider for any questions<sup>7-8</sup>.

#### OTC Medications in Pregnancy

Pregnant women commonly use OTC medications. It has been reported that more than 80% of the women take OTC medication in pregnancy<sup>9-10</sup>. In a recent study regarding the prenatal use of medication, about 53% of the women were reported to take Acetaminophen in the first trimester and about 53% in the last trimester<sup>11</sup>. Although most OTC drugs have an excellent safety profile, some have unproven safety

or are known to adversely affect the fetus. The safety profile of some medications may change according to the gestational age of the fetus. Some of the commonly used OTC drugs such as Acetaminophen, chlorpheniramine are proven to have a good safety profile<sup>12</sup>. Drugs such as aspirin and salicylates should be avoided during the last three months of pregnancy as it can produce harmful effects. Salicylates containing drugs may prolong pregnancy, increase the risk of maternal bleeding during pregnancy<sup>13</sup>. Ibuprofen and Naproxen belonging to the category of NSAID should be avoided as there are risk of developing pulmonary hypertension in fetus<sup>14</sup>.

Most of the cold medications contains expectorant, decongestants, antitussives and mild analgesics. Guaifenesin is used as an expectorant. The studies reported that there was no strong association between Guaifenesin and malformations studied<sup>15</sup>. Diphenhydramine is commonly used as an Antihistamine. It is found to produce some oxytocic effect at higher doses<sup>16</sup>. As most of the fetal defects results from maternal drug exposure<sup>17</sup>, the US Food and Drug Administration has assigned a risk category for each drugs. The use of several OTC medication in pregnancy is summarized in Table 1 and the use of OTC decongestants and non selective antihistamines in pregnancy are indicated in Table 2.

#### Guidelines For Using OTC Medication In Pregnancy

- Always follow the instruction of the doctor before taking any OTC medicines.
- Avoid taking any medicines during the first trimester since it is the period in which development of the facial and various other organs takes place.
- Avoid taking Ibuprofen during the last trimester as it can cause birth defects in newborn.
- Avoid using long acting medicines.
- Avoid combination products<sup>19</sup>.

#### Alcohol and OTC Medication in Adults

OTC drugs though considered safe and effective can cause harmful effects when combined with alcohol in adults. It can remain in the body of adults for a longer time and can cause serious effects. OTC drug-alcohol interactions can result in serious adverse effects in adults and should be avoided<sup>20</sup>. Some of the effects of OTC-alcohol interactions are shown in Table 3.

#### Ageing Population And OTC Medication

Problems associated with ageing, including arthritis and osteoporosis, are key factors underpinning long term demand for products such as analgesics digestive remedies and dietary supplements. Rate of prescription medication use has increased considerably over the last decades. These include intensification of therapy for common chronic medical conditions [eg.diabetes,cardiovascular disease], increased access to medication because of policy changes [eg.medicare Part D and assistance programmes] and growth of generic drug market. The chances of adverse drug reaction is more in older adults because of altered pharmacokinetics, pharmacodynamics, impaired renal function, reduced hepatic blood flow, decreased body lean mass and increased number of medical conditions<sup>21</sup>. Based on a study of over the counter medication use in older population, about 87% of the population has been reported of taking atleast one OTC medications to treat their symptoms<sup>22</sup>. They can interfere with the other medications and can increase the risk of

adverse drug effect. The use of OTC medications in aging population are indicated in Table 4.

#### Ten ways to get most from your OTC medication

Here are 10 important ways to get the most from your OTC medicine.

- Always start by reading the label all of it.
- Look for an OTC medicine that will only treat the symptoms you have.
- Avoid taking these drugs for a longer period of time.
- Know what to avoid while taking an OTC medicine.
- When in doubt, ask before you buy and use an OTC medicine.
- Take the medicine exactly as stated on the label.
- Use extra caution when taking more than one OTC product at a time.
- Don't combine prescription medicines and OTC drugs without talking to your doctor first.
- Make sure that each of your doctors has a list of all the medicines you are taking.
- Always give infants and children OTC medicines that are especially formulated for their age and weight.
- Don't use OTC medicines after their expiry date<sup>24</sup>.

#### CONCLUSION

There are more than thousand over the counter drugs that you buy without a prescription which all have one thing in common, that they are serious medicines that need to be taken with care. There are various risk when these medicines are not taken accordingly. Some may interact with the medicines, food or drinks and may prove to be fatal. That is why it is important to be medically wise every time when you buy and use an over the counter drug. It becomes the part of the community pharmacist to guide and to give all necessary information about OTC drugs. Moreover education about the usage of OTC medicines, the importance of reading the drug label and the possible side effects that may encounter when not taken according to the instructions should be made. Caution should be taken specially when they are used in children, in pregnancy and in older adults. If any symptom associated with the use of OTC medicines is found, discontinue the medication and immediately report to the doctor. So OTC drugs are safer and effective only when they are used at the dosage and frequency as directed on the label.

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**Table 1. Use of OTC medication in pregnancy<sup>18</sup>**

Drug	FDA Risk classification by trimester(1 <sup>st</sup> /2 <sup>nd</sup> /3 <sup>rd</sup> )	Category	Use in pregnancy
Acetaminophen (Tylenol)	B/B/B	Non narcotic analgesic	Recommended choice of Pain reliever.
Aspirin	D/D/D	NSAID analgesic	Not Recommended due to increased risk of maternal bleeding.
Ibuprofen (Advil) Ketoprofen (Orudis) Naproxen (Aleve)	B/B/D	NSAID analgesic	Should be used with caution; Avoid in third trimester( effect on the fetal cardiovascular system)

**Table 2. Use of OTC decongestants non- selective antihistamines in pregnancy**

Drug	FDA pregnancy Risk Classification	Category	Use in pregnancy
Chlorpheniramine (Chlor-Trimeton)	B	Antihistamine	Recommended choice of drug.
Pseudoephedrine Hydrochloride (Novafed)	B	Oral Decongestant	Recommended choice of drug
Guaifenesin (Humibid L.A)	C	Expectorant	Should be avoided in the first trimester
Dextromethorphan hydrobromide (Benylin DM)	C	Non narcotic Antitussive	Safe – Recommended choice.
Diphenhydramine (Benadryl)	B	Antihistamine	May be unsafe- Produce some oxytoxic effect.

**Table 3. Effect of OTC drug- Alcohol interactions**

Drug	Category	Interaction	Effect
Acetaminophen ( Tylenol)	Non narcotic analgesic	Alcohol	Risk of liver damage
Diphenhydramine ( Benadryl)	Antihistamine	Alcohol	Enhance sedation
Aspirin	Non narcotic analgesic	Alcohol	Risk of gastrointestinal bleeding

**Table 4. Use of OTC medication in anti-ageing population<sup>23</sup>**

Drug	Category	Use in Ageing population
Acetaminophen	Non narcotic analgesic	Safe, pain reliever of choice for treatment of osteoarthritis
Aspirin	NSAID	unsafe; Increased risk of gastrointestinal bleeding
Ibuprofen	NSAID	May be unsafe
Diphenhydramine	Antihistamine	Not recommended
Cromylgonium sodium	Antihistamine	Drug of choice for treating Allergic rhinitis