

# Medicines In My Home



Department of Health and Human Services  
Food and Drug Administration

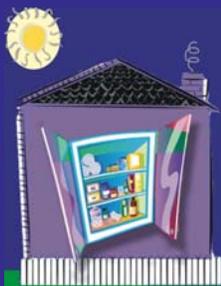


# Medicines in My Home:

An educational program about the  
safe use of OTC medicines

[www.fda.gov/medsinmyhome](http://www.fda.gov/medsinmyhome)

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# Medicines in My Home

## Background and Program Development



# Why do we need to teach Americans about the safe use of medicine?

## Isn't it just common sense?

- Misuse of medicines is common
  - Acetaminophen overdose and liver failure
  - Focus testing and chugging of cold/cough medicine
  - Use of adult formulations for children
  
- Abuse of legal medicines is common
  - Partnership for a Drug Free America now considers legal medicine a *gateway drug* into abuse for teenagers.
  - 2007 DARE America lesson on the misuse and abuse of medicines
    - Fifth grade lesson focuses on correct use of medicines and is based on the MIMH program.



# Why student health education?

Because  
Health Education Works



# MIMH: Concept and Rationale

- Winter/Spring 2004:
  - FDA focus on acetaminophen toxicity
  - Educational campaign about the safe use of OTC medicines in general and acetaminophen in particular.
- June 2004:
  - British drug regulator visits FDA and talks about how Great Britain is addressing consumer safety and the use of OTC medicines.
- Present time
  - FDA focus on Drug Safety and Risk Communication



# A Little Research....

## Self-medication in children

- Two articles suggested that children start to self-medicate at about age 11 or 12 years....sometimes younger.
  - Survey of junior high school students in Nova Scotia  
(Chambers CT et al. Self-administration of Over-the-counter Medication for Pain Among Adolescents. Arch Pediatr Adolesc Med 1997 May; 151: 449 - 55.)
  - Study of medicines that children bring to sleep-away camp  
(Rudolf MCJ et al. Self-Medication in Childhood: Observations at a Residential Summer Camp. Pediatrics 1993 Jun 6; 91(6): 1182 - 84.)
- Children are legally allowed to be home alone at age 12 or 13 years and sometimes take on babysitting responsibilities.



# Promoting and Protecting the Public Health

- FDA is concerned about unintentional or purposeful misuse of OTC medicines
- Education on the safe use of medicines may positively impact public health and safety
  - As education about smoking, alcohol and drug abuse, wearing safety belts, and reproductive education have.
- School health education lessons can indirectly educate entire families.



# MIMH Historical Timeline

- October 2004: Working group formed
- Program developed with:
  - Maryland Montgomery County Public Schools
  - The National Council for Patient Information and Education
- 2005-2006 School Year
  - Pilot program in three middle schools with three health education teachers
  - One class period presentation, part of Safety Unit
  - Website development
- June 2006: Website launch
- May 2007: First website expansion



# Activities since Spring 2007

- Developing new web materials
  - Checklist to use at the store when choosing an OTC medicine for a child
  - Basic information about the drug development and approval process and about approved versus unapproved drugs
  - Seniors' corner within the Consumer Room
  - Information about the misuse and abuse of medicines
- Online interactive program scripted
  - To be developed through a contract



# MIMH lesson: Key Concepts

- The Drug Facts label tells you:
  - What a medicine treats
  - How to use the medicine
  - If the medicine is right for you and your problem.
  
- When you use an over-the-counter medicine,
  - READ the label
  - Follow the label directions carefully and correctly.
  
- Medicines should be used only with permission from a parent or guardian.



# MIMH lesson: Key Concepts

- Two medicines that have the same active ingredient should not be used at the same time.
- Measure your medicine correctly with a measuring tool made for medicines.
- If you or your parent has questions about your medicine, ask your doctor or pharmacist.



Let's take a tour.....



# Learning Objectives

- Understand similarities and differences between prescription and OTC medicines.
- Understand that OTC medicines are serious medicines and can be harmful if directions are not followed.
- Identify
  - The active ingredients in an OTC drug product and what the active ingredients treat.
  - The warnings section and explain why there are warnings on medicine labels
  - The directions section.



## Learning Objectives

- Understand how to correctly measure a dose of medicine.
- Understand that a person should never use two medicines at the same time that contain the same active ingredient
- Understand how to get more information about a medicine
- Understand how to call the Poison Control Center



# MIMH Teachers' Kit

- Pre-test the day before
- Handouts for the beginning of class:
  - Worksheet
  - Drug Facts label and package label for "Feel Better Cold and Fever Suspension"
- Animated PowerPoint presentation
  - Class participation encouraged (lots of Q&A)
- Handouts for the end of class:
  - MIMH booklet
  - Home project
- Lesson reinforcement and assessment
  - Worksheet review
  - Post-test



# Children's Feel Better Cold and Fever Suspension



**Ibuprofen** ► Pain reliever/  
(NSAID) Fever reducer

**Phenylephrine HCL** ►  
Nasal decongestant

Relieves:  
Fever,  
Sore Throat  
Stuffy Nose

Grape Flavor



4 Fl Oz (120 mL)

## Drug Facts

### Active ingredients

(in each 5 ml teaspoonful)

Ibuprofen 100 mg (NSAID)\*.....Pain reliever/  
fever reducer

Pseudoephedrine HCl 15mg.....Nasal decongestant  
\*nonsteroidal anti-inflammatory drug

### Purposes

**Uses** temporarily relieves

- nasal and sinus congestion
- stuffy nose
- head ache
- sore throat
- minor body aches and pains
- fever

### Warnings

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

**Sore throat warning:** Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

### Do not use

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant
- right before or after heart surgery
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI), certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

### Ask a doctor before use if the child has

- problems or serious side effects from taking pain relievers, fever reducers, or nasal decongestants
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- not been drinking fluids
- lost a lot of fluid due to vomiting or diarrhea
- high blood pressure
- heart or kidney disease
- taken a diuretic

### Ask a doctor or pharmacist before use if the child is

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any continuing medical condition
- taking any other drug

## Drug Facts (continued)

### When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- the child does not get any relief during the first day (24 hours) of treatment
- fever, pain, or nasal congestion gets worse or lasts for more than 3 days
- stomach pain or upset gets worse or lasts
- symptoms continue or get worse
- redness or swelling is present in the painful area
- the child gets nervous, dizzy, or sleepless
- any new symptoms appear

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- do not give longer than 10 days, unless directed by a doctor (see Warnings)
- shake well before using
- find right dose on chart below. If possible use weight to dose; otherwise use age.
- use only with enclosed measuring cup
- if needed, repeat dose every 6 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance
- wash dosage cup after each use

#### Dosing Chart

| Weight (lb) | Age (yrs) | Dose (teaspoonful) |
|-------------|-----------|--------------------|
| under 24    | under 2   | ask a doctor       |
| 24-47       | 2 to 5    | 1 tsp              |
| 48-95       | 6 to 11   | 2 tsp              |

### Other information

- do not use if printed neckband is broken or missing
- store at 15-30°C (59-86°F)
- see bottom of box for lot number and expiration date

**Inactive ingredients** acesulfame potassium, citric acid, corn syrup, D&C red #33, FDA&C blue #1, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, xanthan gum

**Questions?** 1-800-123-4567

<http://ChildrensFeelBetter.com>

## Places for more information about OTC medicines

Medicines in My Home: [www.fda.gov/medsinmyhome](http://www.fda.gov/medsinmyhome)

FDA Consumer Medicine Education: [www.fda.gov/usemedicinesafely](http://www.fda.gov/usemedicinesafely)

FDA Drug Information: [www.fda.gov/druginfo@fda.hhs.gov](http://www.fda.gov/druginfo@fda.hhs.gov)  
1-888-INFO-FDA  
1-888-463-6332

National Council on Patient Information and Education  
(NCPPIE): [www.bemedwise.org](http://www.bemedwise.org)

Over-the-Counter Medicines, MedlinePlus, NIH  
[www.nlm.nih.gov/medlineplus/overthecountermedicines.html](http://www.nlm.nih.gov/medlineplus/overthecountermedicines.html)

## Quick info

If someone uses too much medicine, call for help right away.

Doctor's phone number:

Pharmacy phone number:

24 hour Poison Control 1-800-222-1222



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# Medicines In My Home

A guide to safe  
over-the-counter medicine use

## Using over-the-counter medicines safely

A drug or a medicine changes the way your body works or treats or prevents a disease.

Over-the-counter (OTC) medicines are the kind you buy without a prescription. Before you use any medicine, you should always speak to your parent or guardian.

In the United States, all OTC medicines have a *Drug Facts* label. The *Drug Facts* label is there to help you and your family choose and use OTC medicines correctly and safely. All medicines can cause unwanted side effects, even ones you can buy without a prescription. But if you use medicine as directed on the label, you can reduce your chance of side effects.

The *Drug Facts* label tells you the medicine's:

- **Active ingredients** - the parts of the medicine that make it work
- **Purpose** - what the medicine does
- **Uses** - the problems the medicine treats
- **Warnings** -
  - when you should not use a medicine
  - when you should ask a doctor first
  - when you should stop using a medicine
  - how the medicine might make you feel
  - what you should not do while using the medicine
- **Directions** - how to use the medicine safely
- **Inactive Ingredients** - color, flavor, preservative, etc.



## Safer by the dozen - 12 tips for using medicines safely

1. Speak to your parent or guardian before using any medicine.
2. Read the *Drug Facts* label - ALL of it - and follow the directions. Use a medicine only if you know what it is and what it is for.
3. Check the active ingredients in all your medicines. Make sure you don't use two medicines with the same active ingredient at the same time. Too much of an active ingredient can hurt your liver, kidneys, or other parts of you.
4. Choose a medicine that only treats the problems you have. Otherwise, you are using extra medicine you don't need, and it might cause side effects.
5. Tell your parent, guardian, or school nurse if you do not feel better or if you start to feel worse after using a medicine.
6. Use the medicine dose listed on the label. Don't take more. If this dose doesn't help you feel better, talk to your doctor.
7. Use medicine only as long as the label says. If you think you need the medicine for a longer time, talk to your doctor.



## 12 tips for using medicine safely

8. Speak to your doctor, nurse, or pharmacist if you have questions about your medicine or how it should make you feel.
9. Tell your doctor or nurse ALL of the medicines and vitamins you use. Talk to your parent or guardian about keeping a record of what you use. You can use "My Medicine Record" at <http://www.fda.gov/medsinmyhome>.
10. Keep medicine in the bottle, box, or tube that it came in. That will make the directions easy to find.
11. Keep all medicines in a safe, dry place and where they can't be seen or reached by younger children or pets. This helps medicine last longer and prevents medicine accidents.
12. If a medicine is past the expiration date on the package, it may not work as well. Have your parent or guardian throw old medicines away where they can't be reached by younger children and pets.

## About prescription medicine:

Don't use other people's prescription medicine and don't share your prescription medicine with anyone else.

Use your prescription medicine only as directed. If you think you need a change in your medicine, talk to your doctor.

Make sure that your OTC medicines do not contain the same active ingredients as your prescription medicines. Ask your doctor or pharmacist about the active ingredients in prescription medicines.



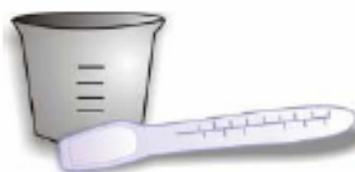
## How to measure your medicine safely

It is important to measure your medicines correctly to get the right dose. Use the measuring spoon, cup, or syringe that comes with your medicine. This is the most exact way to measure your dose.

If your medicine doesn't come with a special measuring tool, ask for one at the pharmacy. A silverware spoon may hold the wrong amount of medicine. Make sure your measuring tool can measure the right dose. Check the markings on the tool.

Most liquid medicines are measured in teaspoons (tsp) and milliliters (ml).

5 ml = 1 teaspoon (tsp)  
15 ml = 3 teaspoons = 1 tablespoon (Tbsp)  
30 ml = 1 fluid ounce (oz)



## Know your weight!

- The *Drug Facts* label lists the right medicine dose for a child by weight or age. Use your weight and age to find your dose.
- If you can, choose the dose by weight - it is more exact. (Children who are the same age can be very different sizes.)
- Never guess a dose. If a dose is not listed on the label for your weight and age, or if you can't tell how much to use, then ask. You and your parent/guardian can ask your pharmacist or doctor about what to do.

# The *Drug Facts* Label

The **Active ingredient/ Purpose** section tells you about the part of your medicine that makes it work – its name, what it does, and how much is in each pill or teaspoon (5 mL).

The **Uses** section tells you about problems the medicine will treat.

The **Warnings** section tells you:

- When you should talk to your doctor first
- How the medicine might make you feel
- When you should stop using the medicine
- When you shouldn't use the medicine at all
- About things you shouldn't do while taking the medicine.

| <b>Drug Facts</b>   |  |
|---|--|
| <b>Active ingredient (in each tablet)</b>   | <b>Purpose</b>   |
| Chlorpheniramine maleate 4 mg.....  | Antihistamine  |
| <b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat  |  |
| <b>Warnings</b><br>Ask a doctor before use if you have<br>■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis<br>■ trouble urinating due to an enlarged prostate gland<br>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives<br>When using this product<br>■ you may get drowsy ■ avoid alcoholic drinks<br>■ alcohol, sedatives, and tranquilizers may increase drowsiness<br>■ be careful when driving a motor vehicle or operating machinery<br>■ excitability may occur, especially in children<br>If pregnant or breast-feeding, ask a health professional before use.<br>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. |  |
| <b>Directions</b>   |  |
| adults and children 12 years and over   | take 1 tablet every 4 to 6 hours;<br>not more than 6 tablets in 24 hours   |
| children 6 years to under 12 years  | take 1/2 tablet every 4 to 6 hours;<br>not more than 3 tablets in 24 hours |
| children under 6 years  | ask a doctor   |
| <b>Other information</b> ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture   |  |
| <b>Inactive ingredients</b> D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch   |  |

The **Warnings** section also tells you:

- To check with a doctor before using medicine if you are pregnant or breastfeeding.
- To keep medicines away from children

The **Directions** tell you how to safely use the medicine:

- How much to use
- How to use it
- How often to use it (how many times per day or how many hours apart)

The **Other Information** section tells you how to keep your medicine when you are not using it.

The **Inactive Ingredients** are mixed with the active ingredient to form a pill, add flavor or color, or help the medicine last longer.



## Common OTC medicines and what they treat

Treating pain and fever are two of the most common reasons people use OTC medicines.

There are five active ingredients used to reduce fever and to treat mild aches and pains caused by headaches, muscle aches, backaches, toothache, the common cold, and menstrual cramps.

- acetaminophen
- aspirin
- ibuprofen
- naproxen sodium
- ketoprofen



The last four active ingredients are all members of a drug family called non-steroidal anti-inflammatory drugs, or NSAIDs for short.

Other health problems can be prevented or treated with OTC medicines. Here are some examples:

- Nasal congestion (decongestants)
- Allergies (antihistamines)
- Cough (cough suppressants and expectorants)
- Stomach Upset (antacids and acid reducers)
- Cigarette addiction (nicotine gum, lozenge, or patch)
- Skin damage from sun (sunscreens)

**Decongestants** treat nasal congestion or stuffy nose. People with high blood pressure or heart disease need to speak with their doctor or nurse before using these medicines.



## Common OTC medicines and what they treat

**Antihistamines** are active ingredients that treat allergy and cold symptoms including: sneezing, runny nose, and itchy, watery eyes.

**Cough suppressants** help you stop coughing or cough less often. An expectorant thins out mucus so you can cough it up more easily.

If OTC medicines are not used as directed on the label, they can be harmful. This is true even for medicines often used to treat pain and fever. For example:

- Acetaminophen can damage your liver, especially if you use more than directed
- Ibuprofen, naproxen, or ketoprofen can damage your kidneys
- Children and teenagers should not take aspirin for fever or flu because it may cause a severe illness called Reye's Syndrome.

### Medicines with more than one active ingredient:

Some OTC medicines are made to treat more than one problem at a time. Examples of these medicines include

- cold and flu medicines
- some allergy medicines
- cough and cold medicines.

Some medicines have more than one active ingredient to treat more than one problem. Choose a medicine that treats only the problems you have. Otherwise, you could get unwanted side effects from medicine you don't even need.

## Is it a drug (medicine) or isn't it?

- Antiperspirants are drugs. They stop your sweat glands from making sweat.

Deodorants are not drugs. They just help your sweat smell better.

- Mouthwash is a medicine when it has active ingredients that reduce plaque and gum disease.

Mouthwash is not a drug if it just makes your breath smell better.

- Dandruff shampoos are drugs because they treat dandruff and itching.

Regular shampoos are not drugs - they only make your hair cleaner.

- Fluoride toothpastes are drugs because they help reduce cavities.

Toothpastes without fluoride are not drugs because they only help clean your teeth.

Read the label each time before you use a medicine.  
Be sure it's right in 5 ways:

- the right medicine
- for the right person
- in the right amount
- at the right time
- in the right way (swallow, chew, apply to skin, etc.)



## Are vitamins, herbals, and other dietary supplements also over-the-counter medicines?

Dietary supplements are not over-the-counter medicines. This can be very confusing.

The part of the Food and Drug Administration (FDA) that controls dietary supplements is the same part that controls foods sold in the United States. Our country's laws are different for medicines and for dietary supplements. Like foods, dietary supplements have *Nutrition Facts* labels - they do not have *Drug Facts* labels.

You can read more important information about dietary supplements at the websites listed below:



Consumer information on Dietary Supplements: frequently asked questions  
<http://www.cfsan.fda.gov/~dms/ds-oview.html>

