

LESSON 2: Reading and Understanding the Drug Facts Label

Students will learn how to properly read a drug facts label.

Students will use visuals to learn how to read the drug facts label.

Grades: 5 and 6

Duration: Two 40-minute class periods

Pre-instructional Planning

OBJECTIVES

Students will:

- Identify the drug facts label
- Learn the definitions of the terms on the drug facts label
- Know the importance of reading and understanding all of the information on the drug facts label
- Learn the potential consequences of not reading and understanding all of the information on the drug facts label
- Identify the steps to take in the event of a medicine mistake

MATERIALS

- FDA's Medicines in My Home video
- Understanding the Drug Facts Label printable
- OTC Medicine Safety Answer Key printable
- Over-the-Counter Medicine Safety Classroom Poster printable
- Find a Drug Facts Label Scavenger Hunt printable
- Medicine Safety for Families Newsletter printable
- Two empty fever-reducer bottles (suggestion: use a liquid product and a solid-dose product)
- Two empty bottles of pain reliever
- Two empty bottles of antacids

- Two empty bags of cough drops
- Paper and pen or pencil
- Computer with Internet access and projector
- **Optional:** Additional empty medicine containers that correspond to the Find a Drug Facts Label Scavenger Hunt printable
- Optional: Whiteboard
- Optional: The Perfect Project Digital Storybook

During Instruction

SET UP

- 1. Before each lesson in the OTC Medicine Safety program, inform students that they should never take medicine without the supervision of a parent or trusted adult.
- 2. Make copies of the printables for each student in your class.
- 3. Set up a projector to show the FDA's Medicines in My Home video and The *Perfect Project* Digital Storybook to your students.

LESSON DIRECTIONS

Step 1: Begin the discussion by challenging students to focus on the overall importance of reading directions. Ask students:

• What could happen if you only read part of the directions on a test?

Discuss responses and emphasize the importance of reading informational text in order to understand key information or directions that are vital to completing a task properly or getting the desired results.

Step 2: Explain that all directions are not the same, meaning that sometimes the directions won't appear at the top of the page like on a test. You may have to look for them, and you should always ask your teacher, parent, or a trusted adult to clarify them so you fully understand what to do.

Step 3: Explain that the class is going to learn about the importance of reading and following all of the instructions found on the drug facts label of OTC medicines.

Step 4: Organize the class into groups of five or six students and give one medicine container to each group. Distribute Understanding the Drug Facts Label printable.

Step 5: Show the <u>FDA's Medicines in My Home video</u> pause it when necessary to highlight the different sections on the drug facts label and have students ask questions. In support of the video, have students look closely at the medicine samples they have in their groups.

Step 6: Before beginning the Understanding the Drug Facts Label PDF, ask students:

- Which medicine does your group have?
- Where are the directions on your group's medicine and what do they tell you?
- Where are the warnings?
- Where is the ingredients section?

Step 7: Explain that directions and drug information for OTC medicines are found on Drug Facts labels, which appear on OTC medicines per FDA regulation.

Step 8: Walk students through each section of the labels on the Understanding the Drug Facts Label PDF. Create a vocabulary list to reinforce new terms, explaining that these terms provide us with the information we need to use medicine responsibly. If you are using a whiteboard, project the image of the Drug Facts Label image onto the board. Review the different sections of the label (use the Over-the-Counter Medicine Safety Classroom Poster printable to support the discussion) and reinforce the new vocabulary words or terms:

Key Terms

- Active Ingredients: The ingredients in the medicine that make it work.
- **Warnings:** Safety information including side effects, the questions you should ask a doctor before taking the medicine, and which medicines to avoid using at the same time.
- Other Information: How to store the medicine.
- Uses: Describes the symptoms that the medicine treats.
- **Directions:** Indicates the amount or dose of medicine to take, how often to take it, and how much you can take in one day.
- **Inactive Ingredients:** Ingredients not intended to treat your symptoms (e.g. preservatives, flavorings).
- Questions or Comments?: Call the company if you have questions about a specific medicine.

Step 9: Add the new terms to the whiteboard as you review each and discuss the definitions. Have students refer to their medicine containers to reinforce these terms.

Step 10: If students need more practice with reading drug facts labels on different medicines, provide an assortment of empty medicine bottles, bags, or boxes, and the Find a Drug Facts Label Scavenger Hunt printable

Step 11: Explain to students that when medicines are not used properly, real consequences, including serious harm, may result. **Reinforce the importance of always communicating with a trusted adult before taking any medicine.** The consequences of using medicine improperly can include:

• Ingredients may cause allergic reactions.

- Medicines can be harmful if you take too much and may not be effective if you do not take the proper dose.
- Certain medicines can interact with other medicines and may cause side effects or harm when mixed.
- Many medicines contain the same active ingredients, and should never be taken at the same time.

Step 12: Discuss how to use the **Poison Help number, 1-800-222-1222**. This number should be used if a student or his or her parent or a trusted adult has questions about how to take or give medicine, if there's been a medicine mistake, or if there's been an accidental ingestion of medicine. Inform students of the following:

- Calls are free.
- Calls are confidential.
- Experts answer the phone 24/7, 365 days a year.
- Unlike 911, it doesn't have to be an emergency to call. Call with questions or for information, or if you have an emergency.
- Poison center experts get more than 3 million calls a year about all kinds of things. They
 have heard everything, so don't be embarrassed to call.

LESSON EXTENSIONS

1. Provide students with the following prompt:

Research the regulation that required drug facts labels to appear on OTC medicines. Write a paragraph to describe the regulation and identify some of the problems that it helped to address.

2. Project *The Perfect Project* Digital Storybook for students to view. Have students discuss what they have learned about the Poison Help number. Post the number in a visible place in their home and encourage family members to save the number in their mobile phones.

HOME CONNECTION

If you haven't already, send home the Medicine Safety for Families Newsletter printable so students may continue the discussion at home.

STUDENT WORKSHEET 2

Understanding the Drug Facts Label

Directions: Think about the discussions you've been having in class about over-the-counter (OTC) medicines and the issues that can arise from not reading and understanding the *Drug Facts* label. Use the sample label on the medicine box pictured here in order to answer the questions below. Write your answers on the back of this sheet.

Think It Through

- 1. What kind of information might be found in the "Do Not Use" section under "Warnings"? Why is it important for someone to see that information?
- **2.** Are there any side effects associated with the use of this medicine?
- 3. According to information on this label, what are some reasons that someone might have to contact a doctor before or after giving this medicine?
- **4.** What section of the label would you refer to in order to determine the correct dose?
- **5.** What is the poison center phone number?

Drug Facts

Active ingredients Purpose Medicine 100 mg cough suppressant Medicine 150 mg nasal decongestant

Uses Temporarily relieves:

- coughing due to minor throat and bronchial irritation
- nasal congestion

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product

- you may get drowsy
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and seek medical help right away if allergic reaction occurs.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

■ Tablet melts in mouth. Can be taken with or without water.

Age	Dose
adults and children 12 years and older	2 tablets every 12 hours; do not use more than 4 tablets in a 24-hour period
	1 tablet every 12 hours; do not use more than 2 tablets in a 24-hour period
children under 6 years of age	ask a doctor

Other information

■ store at 20°-25°C (68°-77°F)

■ keep dry

Inactive ingredients

anhydrous citric acid, aspartame, magnesium stearate, maltodextrin, modified food starch, sodium bicarbonate, D&C yellow no.10

Questions or comments?

Call weekdays from 9 a.m. to 5 p.m. EST at 1-800-XXX-XXXX.

This is not an actual Drug Facts label.

Includes a warning about allergic reactions	Says to take the medicine every 4 to 6 hours	Instructs you to ask a doctor before use	Says to use the medicine to relieve minor aches and pains
Warns that you may get drowsy when using this medicine	Has different instructions for adults and children under 12	Says to store the medicine away from excessive moisture	Lists more than one active ingredient
Says to take the medicine every 8 hours	Includes a sore throat warning	Says to keep the medicine out of reach of children	Says to use the medicine to relieve heartburn

OTC MEDICINE SAFETY

ANSWER KEY

► STUDENT WORKSHEET 1

- 1. Both
- 2. Prescription
- 3. Prescription
- 4. Both
- 5. OTC
- 6. Both
- 7. Both

STUDENT WORKSHEET 2

- 1. Answers might include: mentions of reasons that someone should not take the drug, such as an allergic reaction to the product or any of its ingredients; other products that should not be used while using this product; or other reasons why a person should not take the product. It's important that a person read this information before taking medicine because it can help avoid preventable side effects.
- **2.** Yes. Side effects may include drowsiness and/or excitability, particularly for children.
- 3. Answers may include: A doctor should be consulted before use of this product if you have liver or kidney disease, and for the purposes of administering to children under 6 years of age. A doctor should be consulted if allergic reaction or overdose occurs.
- **4.** The "Directions" section.
- **5.** 1-800-222-1222

STUDENT WORKSHEET 3

- **1.** At 8 a.m. the next day. After that, no more doses should be given until after 8 p.m.
- **2. a.** 2.5 mL **b.** 2.5 mL
- **3.** Utilizing anything other than the dosing device that is packaged with the medicine can result in an inaccurate dose.

- **4.** A *Drug Facts* label might suggest that people contact a doctor before use for a variety of reasons. These reasons may include factors such as age, health conditions, or other medicines they are taking that may require special instruction or may make the medicine inappropriate for certain people.
- **5.** Answers could include a discussion of the information provided on the *Drug Facts* label; use of proper dosing devices; the consequences of not using proper dosing devices; communicating the importance of understanding dosing information.

STUDENT WORKSHEET 4

[Freeform writing. Answers will vary.]

► STUDENT WORKSHEET 5

Any response that identifies medication stored in a location that is not up, away, and out of sight would be acceptable. The medication storage errors shown in the picture are as follows:

- **1.** Bottle of cough medicine on the counter and a teaspoon with a trace of medicine visible on spoon
- **2.** Medicine left out on the nightstand with dosage cup
- **3.** Allergy medicine on the table next to vase
- 4. Toiletry bag hanging low from doorknob inside closet
- **5.** Medicine bottles visible and accessible inside cabinet below kitchen sink
- **6.** Open purse with multivitamin bottle sticking out of the top

OTC MEDICINE SAFETY

ANSWER KEY

(Continued)

PRE-ASSESSMENT QUIZ, POST-ASSESSMENT QUIZ

Q1. PRESCRIPTION MEDICINE	
Q2. OVER-THE-COUNTER (OTC) MEDICINE	
Q3.	
If you use a household or kitchen spoon to measure liquid medicines, you can be sure you will get the right dose.	FALSE
You can't be harmed by over-the-counter medicines. After all, you can buy them without a doctor's prescription.	FALSE
It's okay to take two medicines with the same active ingredient at the same time.	FALSE
It's okay to use someone else's prescription medicine if you have the same symptoms he or she had when he or she got it.	FALSE
It's okay to take your leftover prescription medicine later if you get sick again.	FALSE
It's okay to take more medicine than what is directed on the label if you are very sick.	FALSE
In a medicine, an active ingredient is what relieves a person's symptoms.	TRUE
The <i>Drug Facts</i> label tells you what symptoms the medicine treats.	TRUE
The <i>Drug Facts</i> label gives you the dosage information (how much medicine to take).	TRUE
Q4.	
A pharmacist can answer questions about over-the-counter medicines.	TRUE
All medicines have an expiration date.	TRUE
Children should not use prescription medicine without the permission of their parent or a trusted adult.	TRUE
Medicine should be kept in a place where children can't reach it.	TRUE
If you and your friend are the same age it will be safe for you to take the same dose of an over- the-counter medicine.	FALSE
Prescription medicine cannot be bought without a doctor's permission.	TRUE

OTC MEDICINE SAFETY

ANSWER KEY

(Continued)

PRE-ASSESSMENT QUIZ, POST-ASSESSMENT QUIZ

Q5.	
Children over 12 can take over-the-counter medicine without a parent's permission if they carefully read the label.	FALSE
Medicine should be stored in the container it came in.	
One gulp from a bottle of liquid medicine is exactly one tablespoon of medicine.	
Over-the-counter medicines can be dangerous when misused.	TRUE
Prescription medicine can be found on the shelves in some stores.	
Prescription medicine is meant to be used by one person.	TRUE
Q6.	
The local poison center is a good place to call if someone has taken too much medicine.	TRUE
Medicine should be kept on the kitchen counter so you remember to take it.	FALSE
Taking more medicine than directed will help you feel better faster.	FALSE
Taking more than one medicine with the same active ingredient will help you feel better faster.	FALSE
If you have questions about an over-the-counter medicine you have not taken before, you should ask a friend who has taken it before.	FALSE
You can call the poison center even if it isn't an emergency.	TRUE



OVER-THE-COUNTER MEDICINE SAFETY

UNDERSTANDING THE LABEL

The Drug Facts label helps you understand the medicines that you take and how to take them safely. All medicines should be taken with the direct supervision of a parent or trusted adult.



USES

Describes the symptoms that the medicine treats.





ACTIVE INGREDIENTS

The ingredients in the medicine that make it work.

WARNINGS

Safety information, including

side effects, the questions

you should ask a doctor

medicines to avoid using

OTHER INFORMATION

How to store the

medicine.

before taking the

at the same time.

medicine, and which

Drug Facts

Active ingredients **Purpose** cough suppressant Medicine 150 mg nasal decongestant

Uses Temporarily relieves:

■ coughing due to minor throat and bronchial irritation ■ nasal congestion

Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product

■ you may get drowsy

■ be careful when driving a motor vehicle or operating machinery

excitability may occur, especially in children Stop use and seek medical help right away if allergic reaction

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions

■ Tablet melts in mouth. Can be taken with or without water.

Age	Dose
adults and children 12 years and older	more than 4 tablets in a 24-110di per
ormarer 6 years to under 12 years	1 tablet every 12 hours; do not use more than 2 tablets in a 24-hour period
children under 6 years of age	ask a doctor

Other information

■ store at 20°-25°C (68°-77°F)

■ keep dry

Inactive ingredients

anhydrous citric acid, aspartame, magnesium stearate, maltodex-trin, modification acid, aspartame, magnesium stearate, maltodextrin, modified food starch, sodium bicarbonate, D&C yellow no.10

Questions or comments?

Call weekdays from 9 a.m. to 5 p.m. EST at 1-800-XXX-XXXX.

DIRECTIONS

Indicates the amount or dose of medicine to take, how often to take it, and how much you can take in one day.



INACTIVE INGREDIENTS

Ingredients not intended to treat your symptoms (e.g., preservatives, flavorings)



QUESTIONS OR COMMENTS?

Call the company if you have questions about a specific medicine.



This is not an actual Drug Facts label.

MEASURE IT CORRECTLY

To get an exact measurement, it is important to only use the dosing device that is provided with the medicine. The Drug Facts label tells you how much medicine you should take based on your weight and/or age. Take only one medicine with the same kind of active ingredient at a time.



Household spoons come in various shapes and sizes, which FACT: means they hold different amounts of liquid.

ASK FOR HELP

Always talk with a parent or trusted adult to learn more about the responsible use of all medicines. Other resources include doctors, nurses, and pharmacists as well as your local poison control center.

In 2018, America's poison control centers managed

1.23 MILLION

exposure cases involving children, tweens, and teens. About half of these exposures involved various medicines.¹

Poison Help 1-800-222-1222

DID YOU KNOW?

Poison control centers are staffed with experts including doctors, nurses, and pharmacists who can help answer questions about medicines or can provide help over the phone if you come in contact with a poison. Calls are free and private.





Over 20,000 kids per year need medical help due to medicine mistakes or misuse.*

Download more **FREE** resources: ymiclassroom.com/otcmedsafety-families



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*AAPCC National Poison Data System query parameters: 2011–2016 annual average, ages 0-19, all unintentional and intentional misuse reasons for pharmaceutical exposure, cases en route to a healthcare facility or treatment recommended by a specialist in poison information, all outcomes.

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Keeping Your Children Medicine-Safe

As children get older, they often start to take on more responsibility—at home, at school, and even with their health. That is why it's so important for families to help children learn how to make safe choices.

Over-the-counter (OTC) medicines can be purchased from a store without a doctor's prescription, but they still need to be treated with the same amount of care! It is important to read and follow the *Drug Facts* label every time.

Medicine Action Plan

Create a medicine action plan to help keep everyone safe and healthy! Have your child check off each item as you complete it together.

- ☐ Which adults should your child talk to if he or she is sick and may need medicine? Provide options if a primary caregiver is unavailable.
- ☐ Where will medicines be stored in your home? Remember that they should be up, away, and out of sight!
- ☐ How will you make sure that each medicine and the dosing device it comes with are kept together?
- ☐ How will your family make sure that the child safety caps are locked on all medicines?
- ☐ How will you make sure that visitors keep all of their medicines out of children's reach and sight?
- ☐ Program the Poison Help number into your phone: **1-800-222-1222**. Bookmark the Interactive Poison Help Website: **poisonhelp.org**.

Get to Know Your Medicine Label

Work as a family to learn more about the children's OTC medicines that you have in your home. Answer these questions together:

- What are the active ingredients?
- Are any side effects listed (under "Warnings")?
- ▶ Where is the poison control number on this label?
- ▶ What is the correct dose for your child to take if he or she is sick?
- ► How frequently should your child take the medicine if he or she is sick?
- ▶ Is the dose or frequency different for a younger sibling?
- ► What type of medicine dosing device came with the medicine? (Make sure it is stored with the medicine!)





Medicine Storage and Disposal, Safe Use, and Misuse

Using the correct dose of medicine is a science—too little won't be effective, and too much could be harmful. It's also important to make sure that medicines are stored up, away, and out of sight, as well as disposed of properly (see bit.ly/fda-disposal).

Play the **Hidden Home Hazards** game as a family to learn about safe storage.

Medicine Safety Hunt

How safe is each room in your home? Work together as a family to make sure that all types of health-related items are up and away in a safe location. Look for all of the following:

- **▶** Liquid medicines
- ▶ Pills
- ► Medicated creams
- ► Cough drops
- ► Eye drops
- **▶** Vitamins
- **►** Supplements
- ► Prescription medicines
- ► Other healthcare products or potentially dangerous products, such as detergent pods
- 1. Are all medicines up, away, and out of sight?
- 2. Is the medicine dosing device stored with the medicine?
- **3.** When disposing of a medicine, do you follow the U.S. Food and Drug Administration's guidelines?
- 4. Is any medicine past its expiration date?

What Should You Do?

As a family, read each of the following scenarios about OTC medicines. Is this situation safe? Is this misuse? How should the characters handle the situation?

- Nikita has a headache. Last time she had a headache, her dad gave her some ibuprofen. He isn't home from work yet, so Nikita goes to the medicine cabinet and takes a couple of the pills without talking to her dad.
- Ruben is taking a dose of cough syrup under his mom's supervision. He forgot the dosing device in the cabinet, so he
- grabs a spoon from the kitchen drawer to measure his dose of medicine.
- ► Every day, Angelica takes a once-aday allergy medicine. Her mom always reminds her at breakfast. Today, though, it doesn't seem to be working. At lunchtime, Angelica takes another dose of the medicine so she will feel better faster.





Our OTC Medicine Safety Checklist

☐ Read and follow the <i>Drug Facts</i> label every time.
☐ Measure carefully. Keep the medicine and the dosing device it comes with together. Never use household spoons to measure medicine.
☐ Check that all medicines, vitamins, and supplements are stored up, away, and out of sight of young children. Keep prescription medicines locked away.
☐ Ensure that the child safety caps are locked on all medicines.
☐ Remind visitors to keep luggage, purses, or anything else that might have medicines in it out of children's reach and sight.
☐ Medicines should only be taken with the supervision of an adult or trusted guardian. Communicate with other caregivers to prevent double-dosing errors.
☐ Make sure your children know that using OTC and prescription medicines incorrectly can cause harm.
☐ Program the Poison Help number into your phone: 1-800-222-1222 .
☐ Bookmark the Interactive Poison Help Website: poisonhelp.org .
Emergency Contacts Post these numbers in a prominent place in your home. Remember to save them into your cell phone in case of emergency. Family Doctor Name: Phone Number: Pharmacy Name: Phone Number:
Poison Help Number: 1-800-222-1222 Open 24 hours a day every day of the year. Calls are fast, free, and confidential.

All of these resources and more are available for FREE: ymiclassroom.com/otcmedsafety-families

Interactive Poison Help Website: poisonhelp.org