

How to Read and Understand an Over-the-Counter (OTC) Medication Label

You can buy OTC medications online or in a store without a prescription. Even though these do not require a prescription from your healthcare provider, these medications can still have risks and side effects, so it is important to review these medication labels carefully. To ensure safety, all OTC medications are required by the Food & Drug Administration (FDA) to have certain components within their “Drug Facts” label. The information in the label includes information on active ingredients, intended uses, as well as directions for use. Ask your pharmacist for help if you have questions or need recommendations for an OTC medication.

Example Drug Facts Label: TYLENOL® Extra Strength Coated Tablets

1 Active Ingredient(s) and Purpose:

describes the active ingredient(s) that works to treat your condition or symptom(s). The label also tells you exactly how much of the active ingredient is in each dose. The purpose describes how the medication works in your body. Sometimes OTC medications may have more than one active ingredient.

2 Use(s): describes the intended reason for taking the medication.

3 Warning(s): describes important safety information such as which patients should avoid the medication, possible side effects, medication interactions, when to discontinue use, and contact your healthcare provider.

Drug Facts	
1	Active ingredient (in each caplet) Acetaminophen 500 mg.....Pain reliever/fever reducer
2	Uses - temporarily relieves minor aches and pains due to: - the common cold - backache - toothache - premenstrual and menstrual cramps - temporarily reduces fever
3	Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take - more than 4,000 mg of acetaminophen in 24 hours - with other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: - skin reddening - blisters - rash If a skin reaction occurs, stop use and seek medical help right away. Do not use - with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. - if you are allergic to acetaminophen or any of the inactive ingredients in this product Ask a doctor before use if you have liver disease Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin Stop use and ask a doctor if - pain gets worse or lasts more than 10 days - fever gets worse or lasts more than 3 days - new symptoms occur - redness or swelling is present These could be signs of a serious condition.
Drug Facts (continued)	
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	
Directions do not take more than directed (see overdose warning)	
adults and children 12 years and over	- take 2 caplets every 6 hours while symptoms last - do not take more than 6 caplets in 24 hours, unless directed by a doctor - do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor
Other information - store between 20-25°C (68-77°F) - do not use if carton is opened. Do not use if foil inner seal imprinted with “TYLENOL” is broken or missing	
Inactive ingredients carnauba wax, crospovidone, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, sodium starch glycolate, stearic acid, titanium dioxide	
Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)	

4 Directions: contains instructions on how to take the medication (by mouth, apply on your skin, etc.), how often to take it, and how long to continue the medication. Do not take more than the maximum directed dose. If under the care of a medical professional, directions of administration, frequency and duration may differ from the OTC label. Adults and children may have different directions for use.

5 Other Information: may include details on how to keep the medication safe and out of reach of children.

6 Inactive Ingredient(s): describe substances that are not an active ingredient but help make up the medication formulation.

TYLENOL® is a registered trademark of KENVUE INC. Example shown is for educational purposes only.

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