

SAFE Medicine®

Protect Yourself from Medication Errors

As approval of medical marijuana spreads state by state, labeling problems have led to errors

Today, 33 states plus the District of Columbia (Washington, DC) have legalized medical marijuana (and 11 states plus DC have legalized recreational use of marijuana). Medical marijuana is different than the street product. With medical marijuana, growers must confirm the products' contents, so this information can be passed on to dispensaries and patients. However, each state has its own regulations for medical marijuana. This has resulted in a wide variety of medical marijuana products and safety concerns, particularly with the labeling of these products.

Active Ingredients of Medical Marijuana

The scientific name for medical marijuana is *Cannabis sativa*. Much like the different varieties and tastes of apples, medical marijuana comes in many different strains that produce hundreds of chemicals called cannabinoids. These cannabinoids are produced in varying amounts based in part on the growing conditions.

The two most notable cannabinoids in medical marijuana are tetrahydrocannabinol (THC) and cannabidiol (CBD). THC affects the mind, behavior, and coordination, causing symptoms similar to intoxication such as euphoria (happiness), relaxation, pain relief, and memory impairment. The intensity of these effects tends to be dose-related, so taking too much medical marijuana with high levels of THC may make people feel anxious and uncomfortable. Even when taken in small doses, symptoms similar to intoxication might cause light-headedness, increasing the risk of falls. THC has been linked to marijuana addiction (cannabis use disorder).

CBD does not produce euphoria. Initial studies suggest it may help reduce inflammation, pain, nausea and vomiting, anxiety, and seizures from epilepsy. Unfortunately, when some people cannot immediately feel the effects of CBD, they may take higher doses than they should. Common side effects include headache, diarrhea, restlessness, and sleepiness. CBD has not been linked to marijuana addiction.

continued on page 2—[Medical marijuana](#) >



Figure 1. Notice the inconsistency of liquid medical marijuana product labeling. One is labeled primarily as a ratio (left) while the other is labeled as a percent (right).

Sidebar:

Labeling issue with medical marijuana

A patient in the hospital told a nurse she takes medical marijuana at home for pain and to help her sleep. She showed the bottle of medical marijuana to the nurse. The dropper bottle had a wrap-around label on it (**Figure 1**). The label said it was a 330 mg tincture and listed the contents as a “hybrid” with a 1:10 ratio. Instructions for use were not on the label. The patient stated the bottle contained a 30-day supply and that she takes half a dropperful at bedtime. The dropper had 0.5 mL and 1 mL markings on it.

Brand X	
Medical Marijuana	
330 MG TINCTURE	Hybrid 1:10

Figure 1. Wrap-around label on a dropper bottle of medical marijuana liquid (with the product name replaced with “Brand X”).

So how much THC and CBD did the patient take with each dose? The label does not show how much liquid (mL) equals 330 mg. Since the bottle contained a 30-day supply, the nurse calculated that the full bottle likely contained 15 mL (30 days times each daily dose of 0.5 mL). Thus, the strength of the product might have been 330 mg per 15 mL. But, this is an unreliable way to determine the product strength.

The label also does not say if the ratio of 1:10 is THC:CBD or CBD:THC. So how much THC and CBD are in each dose? When the patient’s husband brought in the box that held the bottle, the label said there was no CBD at all in the product, even though the label said it was a 1:10 ratio of a “hybrid.”

> **Medical marijuana**—continued from page 1

Dosage Forms

Medical marijuana comes in various forms so it can be taken different ways. While each state may approve different forms of medical marijuana, the most common are:

- Liquids and capsules taken by mouth
- Vaporized products that are inhaled
- Sublingual drops that are placed under the tongue (often called tinctures)
- Creams and ointments that are applied to the skin
- Edibles (which are highly discouraged for patients with children in the home)

Confusing Labeling

The amounts of THC and CBD in medical marijuana products must be listed on the label. While the total cannabinoid content must also be included on the label, only the individual quantities of THC and CBD are required. The amounts of THC and CBD are important to know to manage each patient's symptoms. However, the way these are listed on labels is confusing and can lead to errors. Here are just a few examples of how poorly labeled medical marijuana products can lead to errors.

Inconsistent labeling. The amount of THC and CBD in medical marijuana products can be listed as either a ratio or a percent. A ratio shows how much of each major cannabinoid is contained in the product in relation to the other. So, a 5:1 THC to CBD ratio means that there is 5 times more THC than CBD in the product. A percent may show the strength of the THC and CBD contained in the product. But neither the ratio nor the percent simply tell you how many mg of THC and CBD are in each "dose." Worse, there is no requirement to consistently use a percent or ratio on medical marijuana labels (**Figure 1**, page 1). So, even if you learn how to decipher a ratio, for example, your next purchase may list the percent of THC and CBD in the product. This has led to confusion regarding how much to take for each dose.

Variable order of ratios. If the THC and CBD amounts are listed on the label as a ratio, which cannabidiol gets listed first can vary. So the label may list the ratio as CBD:THC or THC:CBD. No federal regulations exist about which to list first, and most state regulations are silent on this issue. The order of THC and CBD in the ratio may differ even between products from the same grower, causing confusion when determining which product to use.

No volume with percent. In place of (or in addition to) ratios, some labels list a percent. This makes it hard to know the amount of THC and CBD in the product. For example, would you be able to easily figure out the amount of THC and CBD in 1 mL of a 0.037% medical marijuana product? It is vital to know the actual mg amount of THC and CBD in each dose. This is especially important for THC, which is most likely to cause both the desirable and undesirable effects. Even when the mg amount of THC and CBD is listed on the label of a liquid medical marijuana product, too often the volume is not included. This makes it hard to figure out how much to take for each dose. For example, would you know



Figure 2. The bottle on the left contains a 10:1 THC:CBD ratio, and the bottle on the right contains a 1:1 ratio. One patient reported frequently confusing these look-alike containers, especially since both bottles were labeled as a 330 mg tincture.

continued on page 3—**Medical marijuana** >

60 seconds SAFETY TIPS

■ **Mistaken identity.** Why is it important for pharmacy staff to ask for your birthdate, address, or other identification every time you pick up a filled prescription? It is a way to help make sure that medicines are handed to the right person.

We continue to receive reports about consumers accidentally receiving another person's medicines. For example, when a consumer went to the pharmacy to pick up her filled prescription, she learned that her medicine had mistakenly been given to someone else with the same last name. This upset her because the other person now knew she took a medicine to treat depression, a fact she was reluctant to share. In another example, twins with different first names but the same last name, birthdates, and addresses were confused. When one of the twins was dropping off a prescription at the pharmacy, he was told that his "other" prescription was ready. The "other" prescription belonged to his twin brother.

▶ **Here's what you can do:** To make sure the filled prescriptions you pick-up from the pharmacy actually belongs to you:

- Always identify yourself using your full name, month and day of birth, and one other piece of information (e.g., home address).
- Before you accept a medicine from the pharmacy, open the bag and check the label on the medicine for your name. This can help detect and correct a possible error before you leave the pharmacy.
- If you are a twin or other multiple, let your healthcare providers know about the possible confusion with your siblings. Having a similar physical appearance, similar names, and the same birthdate, and possibly also sharing the same address, all increase the risk for a mix-up.

■ **Great catch with newborn's medicine.** After nearly 2 weeks in a neonatal intensive care unit, a newborn baby was continued on page 3—**SAFETY TIPS** >

> Medical marijuana—continued from page 2

how much to take if the container simply listed 330 mg on the label instead of 330 mg per 5 mL? The **Sidebar** (right column, page 1) describes an example of how difficult it is to determine how much THC and CBD are in each dose.

Look-alike containers and labels. Look-alike containers and labels have also led to confusion between products containing different ratios of THC and CBD. This is a big problem with products from the same grower because they are often packaged in similar looking containers (**Figure 2**, page 2).

Unlabeled bottles and cartridges. For some liquid products and almost all vapor cartridges, only the outer box is labeled. The bottle or cartridge itself is not labeled at all (**Figure 3**). If the box is discarded or lost, the unlabeled product may be confused with something else.

Missing information. The labels on some medical marijuana products may fail to list important ingredients. Or, the labels may fail to include important information that is needed to properly use the product. For example, the labels on some patches do not note the dose provided by the patch or how long the effects last (duration).



Figure 3. The container taken from the box has no label to identify its contents.

Inaccurate labeling. The only medical marijuana product approved by the US Food and Drug Administration (FDA) is prescription **Epidolex** (**cannabidiol**), which is used to treat seizures. In addition, FDA has approved a synthetic THC product, dronabinol, used to treat nausea and vomiting caused by cancer medicines and loss of appetite in people with human immunodeficiency virus infection (HIV). However, all other forms of medical marijuana are not approved by FDA. Therapy is considered investigational and safety is not fully understood. CBD-only products that are routinely sold on the internet and in stores also have not been evaluated by FDA for potency, purity, or safety. However, there are many reports

of CBD-only products containing either no detectable CBD, or significantly more CBD than is on the label. Furthermore, studies have found that approximately 1 in 5 CBD-only products contains detectable amounts of THC.^{1,2} This means patients may unknowingly become impaired as well as test positive on urine drug screen tests for THC.

▶ **Here's what you can do:** National labeling standards are clearly needed for medical marijuana products to accurately list the THC and CBD contents and concentrations. However, until then, patients need to know how to interpret the label information.

First, the healthcare provider who recommended medical marijuana for you should ideally have also recommended the right dose and frequency of use that would be best for you. But most physicians have very little knowledge about medical marijuana. So, it is best to go to a physician- or pharmacist-run medical marijuana clinic or dispensary to obtain your medical marijuana. That way, a medical professional who specializes in medical marijuana can help you choose the right product and interpret the label information to ensure you get the right dose. Otherwise, you may be overwhelmed by the choices available and get confused by the label information. Ask for

continued on page 4—**Medical marijuana** >

60 SAFETY TIPS continued from page 2

discharged to home with a prescription for liquid **phenobarbital** (20 mg per 5 mL) twice a day to prevent seizures. Before leaving the hospital, the baby's doctor reviewed the prescription with the parents. He made sure the parents knew the baby's dose (6.5 mg) and how much of the liquid medicine to give the baby for each dose (1.6 mL).

When the baby's father brought the medicine home from the pharmacy, he noticed that the label on the bottle said, "**Phenobarbital** 20 mg/5 mL, give 6.5 mL twice a day." He became concerned because he remembered the doctor telling him the baby's dose was 6.5 mg, and the amount of medicine for each dose would be 1.6 mL. He called the pharmacy and asked for a copy of the prescription the doctor had sent electronically to the pharmacy. When he received it, he noticed that the baby's year of birth was incorrectly listed as 1985. Thus, he presumed the pharmacist had thought the **phenobarbital** was for an adult, not a 2-week-old baby.

The father then emailed a picture of the label on the prescription bottle to the doctor. The doctor agreed that the pharmacy had made an error. He confirmed that the baby's dose was 6.5 mg, and that each twice-daily dose required 1.6 mL of the liquid medicine.

Community pharmacies typically make very few errors when dispensing the billions of medications prescribed annually. However, when errors are made, mistaking the mg dose for the mL volume of a liquid medicine is a fairly common mistake. Five mg becomes 5 mL, 10 mg becomes 10 mL, and in this case, 6.5 mg became 6.5 mL. These errors can be serious, especially for young babies. In this case, had the father given his baby 6.5 mL, it would have resulted in a dose of 26 mg, not the prescribed dose of 6.5 mg. This 4-fold overdose could have caused the baby to slow or stop breathing.

▶ **Here's what you can do:** This great catch is an example of why it is so important to make sure you understand all the discharge medicines prescribed for you continued on page 4—**SAFETY TIPS** >

> **Medical marijuana**—continued from page 3

a demonstration of how to measure each dose of the product you select. Repeat the directions back to the medical professional to confirm you understand. You should also ask for written instructions so you don't have to remember how to take each dose. You can also verify the amounts of THC and CBD in your product using the dispensary online menu to be sure it contains the amounts you need.

If you already have a container of medical marijuana and are uncertain how to read the label, take the container to a medical marijuana dispensary and ask questions. Remember, salespeople (wellness associates) at a dispensary are doing the best they can, but their level of training may not be at the same level as a medical professional with specialized knowledge of medical marijuana.

If the actual bottle or cartridge is unlabeled, keep it in the labeled carton so it can always be identified. Some growers include a sticker you can place on the bottle or cartridge.

Finally, when using medical marijuana products, consider keeping a journal to write down how you are responding to each product and the timing of doses. This information can be useful to adjust your instructions if needed. Also, be sure to try only one new product at a time to make sure you can tolerate it and that it is working.

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Advice from

Warning letter sent to Dollar Tree stores for receiving potentially unsafe drugs

The US Food and Drug Administration (FDA) recently issued a warning (www.ismp.org/ext/326) to Greenbrier International, the company doing business as Dollar Tree. The company had been receiving over-the-counter (OTC) medicines made by foreign manufacturers that violated federal laws. The foreign manufacturers were not testing for contaminants or verifying the quality of the raw materials used to make the products. These manufacturers produced Dollar Tree's *Assured Brand* OTC medicines and other products sold at Dollar Tree and Family Dollar stores.

The warning letter shows a pattern of violations by the foreign manufacturers and outlines steps Dollar Tree needs to take to correct the issue. FDA requested the company to implement a system to ensure they do not import unsafe medicines.

▶ **Here's what you can do:** If you recently purchased *Assured Brand* OTC medicines from Dollar Tree or Family Dollar, do not use the medicines. You can either return them to the store or discard them.



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60 SAFETY TIPS continued from page 3

or your loved one. In this case, the doctor reviewed the **phenobarbital** prescription with the parents prior to discharge, and the father was able to remember these instructions. But it is safest to make sure the prescription details are on the discharge paperwork, so you don't have to rely on memory of the verbal instructions. Also keep in mind, had the father talked to the pharmacist when he picked up the filled prescription, the error would likely have been caught in the pharmacy before going home. Always ask to talk to the pharmacist, especially when picking up filled prescriptions for new medicines.

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