



Private-Label Topicals (PLTs)

RELEVANCE IN WORKERS' COMP

Private-label topicals (PLTs) are independently manufactured products for the temporary relief of minor pain associated with injury, including back and shoulder pain. PLTs are most often dispensed by physicians and come in various formulations such as creams, gels, lotions and patches.

Though PLTs are marketed as superior alternatives to prescription medications and over-the-counter (OTC) products, they offer virtually no clinical advantages and are much more expensive.

AT A GLANCE

- ▶ PLTs are not FDA approved and can even come with safety risks
- ▶ No controlled clinical trials prove the efficacy of PLTs
- ▶ The marketing of PLTs implies clinical advantages over OTC products and prescription medications
- ▶ PLTs are significantly more expensive than similar OTC products

Implications in Workers' Compensation

Although private-label topicals typically represent a small percentage of medications prescribed in workers' compensation, they can have a significant impact on patient safety, as well as cost for the payer.

SAFETY

Many PLTs contain ingredient concentrations in excess of the FDA's maximum recommended concentrations. Furthermore, the FDA also reported that high concentrations of menthol, capsaicin, and methyl salicylate – ingredients common in many PLTs – increase the likelihood of serious skin burns.¹ No studies or clinical trials are available to support the safety or effectiveness of PLTs, and PLTs are not recommended by evidence-based guidelines



Many PLTs also contain concentrations **in excess** of the FDA's **maximum recommended concentrations**.

EFFICACY

Manufacturers market PLTs as having unique formulations and special ingredient blends – implying clinical superiority – despite containing similar ingredients to OTC products and prescription medications. Manufacturers also frequently label PLTs as products that require a prescription, when in fact, because they are not FDA approved, they do not require a prescription. Many also believe that the presence of a national drug code (NDC) means that PLTs are FDA approved, which could attest to efficacy and justify a higher price, but an NDC code does not constitute FDA approval.

Furthermore, PLTs are given brand names such as Medi-Derm®, Medrox®, and Terocin® to imply legitimacy, as opposed to consumer-friendly names like IcyHot® and BenGay®. Research shows that physicians will recommend an OTC medication before a prescription product, as long as they believe both products to have comparable efficacy.³ However, the marketing of PLTs may lead physicians to believe they are providing a superior product.

Limited consumer access may also imply clinical superiority since PLTs are not available OTC. They are typically dispensed in-office from physicians or by smaller, independent pharmacies, often at much higher prices, which could imply higher quality.

COST

Despite having no proven clinical advantages, the average PLT costs over \$500 while the average comparable OTC topical is roughly \$10.00. PLTs can cost up to 100x the amount of comparable OTC products, even though the ingredient makeup of PLTs overlaps heavily with inexpensive OTC products.

For example, Tru-micin® (PLT) and Aspercreme® (OTC) both contain the active ingredient trolamine salicylate with a 10% concentration. However, Tru-micin is over fifty times the cost.



Both products share the **same active ingredient** and concentration, trolamine salicylate 10%.

Physician dispensing of PLTs has doubled since 2012,³ and physician dispensing is associated with higher costs and more lost time than pharmacy-dispensed medication in workers' comp claims.⁴

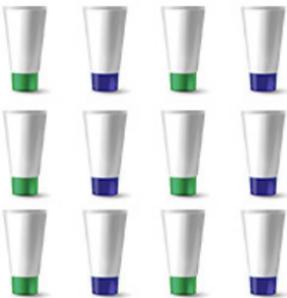
Key Points About PLTs

- ▶ They are **not** FDA approved
- ▶ They do **not** require a prescription
- ▶ They are **not** tested for safety and efficacy
- ▶ They are **not** found in most retail stores
- ▶ PLTs **do** cost significantly more than similar OTC products
- ▶ PLTs **do** pose increased risks for skin burns due to high concentrations of certain ingredients
- ▶ PLTs **do** try to imply clinical legitimacy with designated brand names that sound similar to prescription products names
- ▶ PLTs **do** contain ingredients similar to OTC products, such as
 - Menthol
 - Methyl salicylate
 - Lidocaine
 - Capsaicin
 - Camphor

PLTs ARE NOT COMPOUNDS

Both PLTs and compounds can incur patient safety risks and excessive costs, but they are different.

PLTs are commercially made, mass produced, non-prescription products.

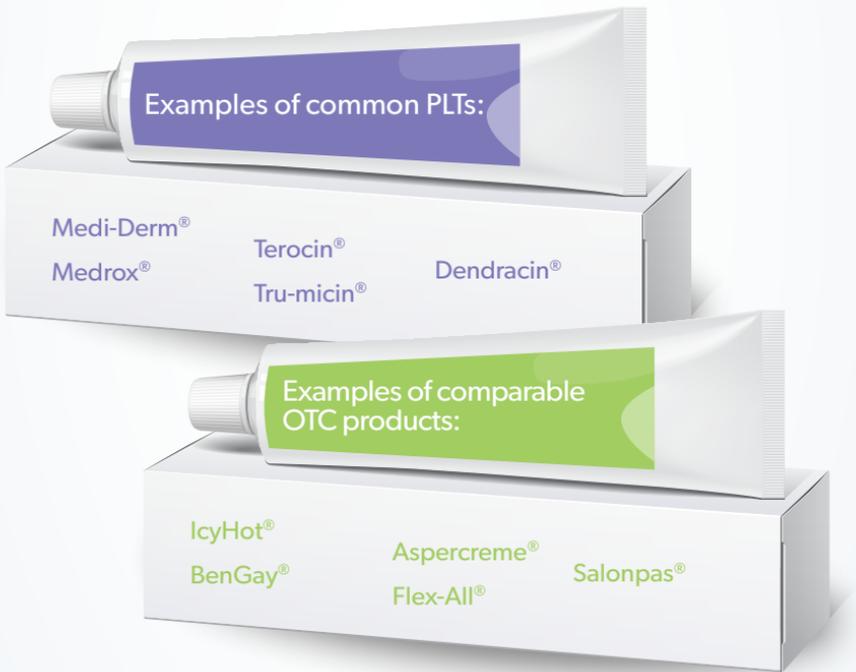


Compounds are made on-demand by a pharmacist based upon an individual prescription.



Recommendations for Private-Label Topicals

- ▶ Educate prescribers and injured workers of the efficacy, safety and cost considerations for PLTs
- ▶ Recognize dispensing trends from physicians and independent pharmacies
- ▶ Request a letter of medical necessity (LOMN) for PLTs
- ▶ Become familiar with existing PLT brands and appropriate OTC alternatives



References

1. FDA Drug Safety Communication: Rare cases of serious burns with use of over-the-counter topical muscle and joint pain relievers. September 2012. Rockville, MD: US Food and Drug Administration. <http://www.fda.gov/drugs/drugsafety/ucm318858.htm>. Accessed May 2016.
2. Consumer Healthcare Products Association. Your health at hand: perceptions of over-the-counter medicine in the U.S. November 2010. http://www.yourhealthathand.org/images/uploads/CHPA_YHH_Survey_062011.pdf. Accessed May 2016.
3. Healthsystems Data
4. White JA et al. Effects of physician-dispensed medication on workers' compensation claim outcomes in the state of Illinois. *J Occup Med.* 2014;56:459-64. al meningitis and other infections. <http://www.cdc.gov/hai/outbreaks/meningitis.html>. Accessed May 2, 2016.

Other Resources

Healthsystems. Compounds and PLTs. *RxInformer* journal. Summer 2016. <https://rxinformer.healthsystems.com/article.php?id=135>

Healthsystems. Private-Label Topicals: A Growing Prescribing Trend in Workers' Compensation. May 2015. <http://healthsystems.com/home/infographics>

Healthsystems. Private-Label Topicals: Over-The-Counter Analgesics Go Undercover As Pricey Prescriptions. *RxInformer* journal. Spring 2015. <https://rxinformer.healthsystems.com/article.php?id=73>

Healthsystems. Topical Analgesics: Expensive and Avoidable. *RxInformer* journal. Fall 2013. <https://rxinformer.healthsystems.com/article.php?id=50>

Three ways to contact a Healthsystems pharmacist for more information:

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