



# Compounds

## RELEVANCE IN WORKERS' COMP

A compound is a product a pharmacist makes for a patient when a medical need exists and a product approved by the U.S. Food and Drug Administration (FDA) cannot be used. A compound combines, mixes, or alters the ingredients of a drug to create a medication for an individual patient. For example, a compound may be a liquid form of a drug that is typically only available in a tablet or capsule. This may be appropriate if the patient is unable to swallow the tablet or capsule.<sup>1</sup>

Unfortunately, the usage of compounds in workers' compensation is often exploited.

## AT A GLANCE

- ▶ Compounds most commonly prescribed in workers' compensation are topical creams, gels, and ointments that are applied to the skin and are intended to manage pain
- ▶ Compounds have not been tested for safety or efficacy and therefore may present a number of potential risks to patients
- ▶ Most compounded products are excessively overpriced in comparison to FDA-approved products

## Implications in Workers' Compensation

Although topical compounds 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

Compounds do not undergo clinical trials for safety or efficacy the way that FDA-approved products do. Although the ingredients used in compounded medications are sometimes similar to commercially available topical products, they are often compounded at much higher concentrations, which may pose a threat to patient safety. This may be due to the patient receiving a higher-than-appropriate dose. In other cases, high concentrations of ingredients that are often found in topical pain creams, such as menthol or methyl salicylate, can burn the skin.<sup>2</sup>

Compounds also typically contain a large number of ingredients (often between 4 and 10). Sometimes a compound will even contain multiple ingredients with the same effect, which is called *therapeutic duplication*. Often there are concerns regarding drug-drug interactions or therapeutic duplication between the ingredients included in a topical compound and additional, oral medications that may have been prescribed.

Contamination of products is also a concern, if the compound is made using poor quality practices.



Compounds are often made with between **4 and 10 ingredients**, often resulting in unnecessary duplicative effects



### EFFECTIVENESS

Many of the drugs contained in topical compounds are **only** FDA-approved for oral use. Therefore, they are likely ineffective when applied to the skin because of how they work in the body. Furthermore, compounds that contain multiple medications with the same effect may increase safety risks without any increase in benefit.

COST

There are situations where there exists a legitimate medical need for a compound. However, in many cases, the compounds prescribed to injured workers would be better replaced with a commercially available topical agent.

Unfortunately, there are compounding pharmacies that exploit the workers’ comp system for financial benefit. In some cases, the pharmacist may select expensive ingredients that unnecessarily inflate the cost of the compound when lower cost, therapeutically equivalent ingredients are available. Below are some examples of ingredients with comparable therapeutic effects, but vastly different costs.

EXPENSIVE CORTICOSTEROID POWDER

FLUTICASONE



AWP  
\$3,000 - \$4,200/g

COMPARABLE ALTERNATIVES

TRIAMCINOLONE



AWP  
\$20-\$95/g

CLOBETASOL



AWP  
\$150 - \$600/g

EXPENSIVE NSAID PRODUCT

TORADOL



AWP  
\$150-\$3,000/g

COMPARABLE ALTERNATIVES

VOLTAREN 1% GEL



AWP  
\$.50/g

DICLOFENAC BULK



AWP  
~\$15/g

## Recommendations for Topical Compounds

Experimental compounds are not recommended by evidence-based treatment guidelines. Use of topical compounds for pain should be critically evaluated and other FDA-approved agents should be used instead.

### FDA-APPROVED, COMMERCIALY AVAILABLE ALTERNATIVES:

Drug class	Generic Name (brand name)	Average Wholesale Price
NSAID	Diclofenac 1% gel (Voltaren®)	\$0.50 per gram
Topical anesthetic	Lidocaine gel, cream, ointment; various strengths 0.5% - 5%	\$0.50 – \$8.50 per gram; depending on strength and form
Topical corticosteroid	Fluticasone 0.05% cream or 0.005% ointment (Cutivate®)	\$1.14 per gram
	Triamcinolone 0.025%, 0.05%, 0.1%, 0.5% ointment and 0.025%, 0.1%, 0.5% cream	\$0.20 – \$0.40 per gram

### CLAIMS PROFESSIONALS SHOULD CONSIDER:

- ▶ What is the intended use of the compound?
- ▶ Are the ingredients found in the compound available in FDA-approved products? Have those FDA-approved products been tried in the past?
- ▶ Has proof of medical necessity been provided that verifies conventional therapy has been tried and failed?
- ▶ Does the patient have a documented allergy to an ingredient in a commercially available topical product?
- ▶ Has the pharmacist or prescriber provided safety and efficacy data for this particular admixture?

## Noteworthy



In rare instances,  
**EXCESSIVE**  
concentrations  
of topical lidocaine  
have caused  
**DEATH**<sup>3</sup>

A MONTH'S SUPPLY OF SOME



**prescription**  
**compounds**  
can cost  
**\$1,000+**



A 2012 fungal meningitis  
**OUTBREAK DUE TO**  
contaminated steroid  
injections at a compounding  
center led to **more than**  
**60 deaths**<sup>4</sup>

Some compounds contain  
concentrations of NSAIDs



**10-30x the FDA-**  
**APPROVED DOSE**  
**FOR TOPICAL USE**

## References

1. Pharmacy Compounding and the FDA: Questions and Answers. Rockville, MD: U.S. Food and Drug Administration. <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm>. Accessed May 2, 2016.
2. FDA Drug Safety Communication: Rare cases of serious skin 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 2, 2016.
3. Death prompts calls for more drug scrutiny. <http://abcnews.go.com/Primetime/Health/story?id=692826&page=1>. Accessed May 2, 2016.
4. Centers for Disease Control and Prevention. Multistate outbreak of fungal meningitis and other infections. <http://www.cdc.gov/hai/outbreaks/meningitis.html>. Accessed May 2, 2016.

## Other Resources

Healthesystems. Compounding trends are cause for concern. *RxInformer* journal. Fall 2014. <https://rxinformer.healthsystems.com/article.php?id=65>

Healthesystems. Topical analgesics: expensive and avoidable. *RxInformer* journal. Fall 2013. <https://rxinformer.healthsystems.com/article.php?id=50>

### Three ways to contact a Healthesystems pharmacist for more information:

 [healthsystems.com/AskAPharmacist](http://healthsystems.com/AskAPharmacist)

 [DrugInfo@healthsystems.com](mailto:DrugInfo@healthsystems.com)

 866.646.2838

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