

First Script Prescription Benefit News for Workers' Compensation

June 2020



Ask The Pharmacist

To suggest a topic, send an email to:
AskThePharmacist@cvty.us.com

What are the advantages and limitations of topical vs. systemic pain medications?

The medication management of chronic pain can be challenging for any number of reasons. The experience of pain among individuals and the evaluation of ongoing treatment effectiveness among caregivers may vary greatly. A large number of available analgesic medications with

wide-ranging indications for use, differing safety and efficacy profiles, a fast-changing regulatory environment, and overlapping disease conditions all contribute to the challenge of delivering safe and effective relief for those with chronic pain conditions. An estimated 20.4% of U.S. adults (50 million) suffer with chronic pain and 8% (19.6 million) have high-impact chronic pain which frequently limits life or work activities.¹

Oral medications are a long-standing standard of care for the management of pain, but they also carry serious risks associated with “whole body” (systemic) exposure to drugs administered by this route. For example, acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), and opioids all have risks when administered orally that are serious and well documented. On the promise of delivering equal or greater efficacy and reducing the risk of adverse events, alternate routes of drug delivery and formulations have been developed.

Topical administration of medication offers an alternative to oral drugs for a smaller number of approved uses. They are locally applied to an affected body area or joint on the skin surface and may be free of side effects due to their limited distribution in the body.

The effectiveness of a topical medication depends greatly on the penetration of the active ingredient through the dermal barrier. A variety of formulations for application to the surface of the skin or a mucus membrane are available. Prescription and over-the-counter (OTC) versions of creams, lotions, ointments, gels, suspensions, foams, powders, and aerosols offer differences in the extent of dermal occlusion (penetration of the active ingredient) and cosmetic acceptability.² Other patient and product factors may influence the amount of active ingredient delivered across the skin, including skin thickness, skin barrier status, occlusion, active ingredient molecule size, fat solubility, and concentration in the preparation.³

Active ingredients commonly incorporated in topical products include local anesthetics (e.g., lidocaine), NSAIDs (e.g., diclofenac), counterirritants (e.g., capsaicin, menthol, camphor, methyl salicylate, and others). Some topicals incorporate carrier molecules like dimethylsulfoxide (DMSO), which increase skin penetration and resulting tissue concentrations.³

In general, the advantages of topical analgesics might include:⁴

- A lower risk of systemic adverse events, side effects, and drug interactions
- A lower dose of active ingredient may be used to achieve a local effect
- Reduced potential for disruption of gut flora or function
- Ease of administration in pill averse, dysphagic, very elderly or very young patients

The disadvantages would be:

- Potential for chemical or allergic irritation (contact dermatitis)
- Insufficient or variable penetration of active ingredient at affected area
- Systemic absorption and related side effects
- Messy, time consuming, or inconvenient to apply

[The Official Disability Guidelines](#) (ODG) and other expert pain treatment guidelines recognize the appropriate use of some topical analgesics as an option in pain management, based on the targeted condition, body site, available evidence for effectiveness, and duration of use. The cost of custom compounded or private-label topical products can be significantly greater than similar, competing OTC, or prescription topicals, and are the subject of regular formulary review and Smart PA alerts for First Script clients.

1. Dahlhamer J, et.al. Morbidity and Mortality Weekly Report – Prevalence of Chronic Pain and High Impact Chronic Pain Among Adults – US, 2016. – September 14, 2018; 67(36):1001-1106 Accessed on June 20, 2020 at https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm#T1_down

2. US Pharmacopeial Convention, Inc. – Accessed at : https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/transdermalStimArticle.pdf

3. Sarbacker, GB - Topical therapies for chronic pain management USPharmacist 2015;40(3):35-38 . Accessed on June 4, 2020 at: <https://www.uspharmacist.com/article/topical-therapies-for-chronic-pain-management-a-review-of-diclofenac-and-lidocaine>

4. Wick, JY – Topical Analgesics Provide Pain Relief - Pharmacy Times Sept2019 Accessed on June 5, 2020 at: <https://www.pharmacytimes.com/publications/issue/2019/September2019/topical-analgesics-provide-pain-relief>

Drug of the Month

ELYXYB™ (Celecoxib Oral Solution 25mg/ml)

On May 6, 2020, the U.S. Food and Drug Administration (FDA) announced the approval of a liquid formulation of celecoxib, ELYXYB (celecoxib oral solution 25mg/ml) for the acute treatment of migraine with or without aura in adults.¹ Celecoxib, a COX-2 selective NSAID, was first approved for use in the U.S. in 1998 and is broadly available in brand and generic versions for a wide range of pain indications, including management of the signs and symptoms of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, the management of acute pain in adults, and the management of primary dysmenorrhea.

ELYXYB solution is formulated using a drug delivery system that enhances the rapid solubility, absorption, and bioavailability of the active ingredient, celecoxib.¹ This allows for the use of lower doses of the active ingredient to achieve therapeutic concentrations.

In clinical trials submitted to support the approval application for ELYXYB, the medication demonstrated a rapid onset of action and treatment effectiveness for acute migraine episodes. A rapid onset of action is an important feature for treatments used in the management of migraine episodes in progress.

ELYXYB is not indicated for preventative treatment of migraine and the product labeling is inclusive of all the same warnings and precautions as other celecoxib products. The more serious among these are “black box” warnings for cardiovascular thrombotic events, gastrointestinal bleeding, ulceration and perforation. ELYXYB is also contraindicated in the setting of Coronary Artery Bypass Graft (CABG) surgery, for patients with a history of asthma, urticarial, or other allergic type reactions to aspirin or other NSAIDs, or who have demonstrated allergic-type reactions to sulfonamide drugs.²

The usual dose of ELYXYB is 120mg, orally, with a maximum dosage of 120mg per day. Dose modifications are described for patients with impaired liver function or who are known to be slow metabolizers for the liver metabolic pathway (CYP2C9).²

Dr. Reddy's Laboratories³ is working to commercialize ELYXYB through U.S. partnerships. Information related to a retail launch and pricing was unavailable at the time of this publication.

First Script will continue to anticipate the commercial arrival of ELYXYB and will evaluate the medication for formulary positioning and related access management.

1. Dr. Reddy's Laboratories – Press Release May 6, 2020 ELYXYB™ – Accessed on June 5, 2020 at: https://www.drreddys.com/media/904710/press-release_elyxyb.pdf
2. ELYXYB™ - Highlights of Prescribing Information – Accessed on June 8, 2020 at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212157s000lbl.pdf
3. <https://www.drreddys.com/>



Governmental Activity by State

Find out more about the governmental updates and potential changes currently being proposed in your state

To find out more about the governmental updates and potential changes currently being proposed in your state, visit the [Coventry News and Insights page](#) each month to read our Government Relations Newsletter. Find this month's newsletter [here](#).

Clinical Updates

Annual First Script Drug Trends Analysis

Coventry is kicking off our annual Drug Trends Analysis with a look at retail and mail-order prescriptions. Following years of decline, this year's infographic illustrates a slight upward trend. Check out [part one](#) to learn more.

Clinical Bulletin: Zoloft® Shortages

On May 29th, the FDA added antidepressant Zoloft (sertraline), along with several of its generic equivalents, to their list of medications reporting current shortages of supply. To find out more, read the [First Script Bulletin](#).

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