

Formulary Drug Listing Decisions

COMPOUNDED TOPICAL ANALGESICS

Indications

Compounded topical analgesics have not been approved by Health Canada and thus have no official indication for the topical treatment of pain.

Formulary Status

The Drug Advisory Committee (DAC) recommended that compounded topical analgesics NOT be listed on any WSIB drug formulary.

The WSIB has decided to accept the DAC recommendation.

Compounded topical analgesics are not listed on any WSIB drug formulary.

Overview

- Topical analgesics amitriptyline, baclofen, gabapentin, pregabalin, cyclobenzaprine, clonidine, ketamine, ketoprofen, naproxen, flurbiprofen, piroxicam, and magnesium do not have Health Canada approval for topical use.
- Capsaicin, lidocaine, menthol and diclofenac have approval from Health Canada for topical use only as ingredients of commercially available topical analgesics, not as compounded formulations of varying potency.
- The DAC considered an external, independent review of the clinical efficacy of compounded topical analgesics in the treatment of pain. The review focused on identifying high quality level evidence such as randomized controlled trials (RCTs). Lower quality evidence was also included in the review due to lack of RCTs. Most of the included studies used placebo as a comparator. Active comparator- trials are limited. The evidence does not support the use of compounded topical analgesics with single ingredient or in combination.

- As there is either a complete absence of studies or very poor quality studies on the exact mixtures of active and inactive ingredients, no conclusions can be reached on skin penetration, bioavailability, physical and chemical stability of the preparations.
- No trials were found to compare compounded topical analgesics with the standard of care in chronic pain conditions relevant to the WSIB.
- Long-term use of compounded topical analgesics and outcomes such as patient well-being, cost-effectiveness or quality of life have not been investigated.
- Adverse effects of the treatment can include local skin rashes, itchiness and irritations.
- Compounded topical analgesics are not included in any guidelines for the treatment of acute or chronic pain.
- The Ontario Drug Benefit Program does not list compounded topical analgesics on the provincial formulary.
- Alternative and less costly analgesics are available on the WSIB formularies that meet the treatment needs of the majority of injured workers.
- Based on the available evidence, the DAC concluded there was very limited evidence to support the use of compounded topical analgesics in the treatment of CNCP.

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Drug Profile

Compounded topical analgesics are extemporaneous preparations (mixtures prepared by pharmacy according to the directions of a prescription) of a drug or combination of drugs for relief of pain.