



Safety Alert: Risks associated with Ophthalmic Anesthetics

The self-administration of ophthalmic anesthetics by patients for the relief of eye pain should be avoided and they should not be given to patients to take home for pain relief. Vision threatening complications of topical anesthetic abuse are common. There is no indication for the use of ophthalmic anesthetics except for diagnostic and short term therapeutic purposes (the removal of a foreign body or ocular surgery) and therefore, these products should only be used under a physician's supervision.

Eye trauma resulting in a corneal abrasion (epithelial injury) is a common complaint in the Emergency department (1). A superficial corneal injury can cause intense pain causing a patient to seek medical help or immediate relief from available over the counter remedies.

In Canada, only two topical ophthalmic anesthetic drugs are available commercially as single entities, proparacaine (proxymetacaine) and tetracaine (available in bottle and minim forms). Benoxinate (oxybuprocaine) is only available in combination with fluorescein (3). Lidocaine is also used in ophthalmic surgical procedures however, it is not available in the Canadian market as an ophthalmic preparation.

Topical ophthalmic anesthetics function by blocking nerve conduction when applied to the cornea and conjunctiva. The ocular surface is innervated by the multiple branches of the trigeminal nerve. The cornea is supplied by the long and short ciliary nerves, the nasociliary nerve and the lacrimal nerve (4). Topical anesthetics reduce sodium permeability preventing generation and conduction of nerve impulses, increasing excitation threshold, and slowing the nerve impulse propagation. This action of the anesthetic prevents conduction along the axons, keeping the brain from detecting painful stimuli (2,5).

Topical ophthalmic anesthetics tend to be used in a clinical setting for the initial assessment of eye trauma, the removal of superficial foreign bodies, ophthalmic surgery and the measurement of intraocular pressure using applanation tonometry. Therefore, many ophthalmic visits can include topical anesthetic administration. In this type of clinical setting the patient will usually only receive one application of topical ophthalmic anesthetic and repeated applications are usually avoided if possible (5,6). Repeated use of topical ophthalmic anesthetic either in frequency of application or length of time of use, can result in serious ocular complications (2).

Patients will apply the topical anesthetic for relief of the initial injury/disease, followed with further use, and leading to tachyphylaxis requiring increased dosing. This may result in induced toxicity causing further pain (12).

Topical ophthalmic anesthetic toxicity has been documented in numerous reports when used inappropriately (2, 7-12). Topical ophthalmic anesthetic toxicity is associated with corneal complications that include persistent epithelial defects, stromal edema and infiltrates, resulting in the classical ring shaped infiltrate, endothelial damage, corneal ulceration, thinning and even perforation. The resulting damage can require full thickness corneal transplantation or enucleation i.e., removal of the eye (2).

In Canada, proparacaine (proxymetacaine), tetracaine and benoxinate (oxybuprocaine) in combination with fluorescein, have been designated in a bottle format as ethical products. However, tetracaine in the minim format has been designated as an OTC (over the counter) product (3). According to federal regulations the following are the definitions for OTC and Ethical drugs:

- 1) **Over the Counter (OTC) / Homeopathic:** Drugs that do not appear on a schedule or are not recommended to appear on any schedule.
- 2) **Ethical:** a drug that in accordance with Federal Legislation does not require a prescription, but that is generally prescribed by a medical practitioner. Ethical products are unscheduled nonprescription professional use products (e.g., MRI contrast agents and hemodialysis solutions) and a few emergency use products (e.g., nitroglycerine) (3).

Most ethical drugs and some OTC drugs are further classified within the NAPRA National Drug Schedules (NDS). In the case of all of these ophthalmic anesthetic drug products (including tetracaine in the minim format), they have been further designated as Schedule II drug products in the NDS. In keeping with the [Standards of Practice for Schedule II Drugs](#), these drugs must be stored behind the dispensary in an area that does not allow for self-selection by patients and the pharmacist must intervene in the sale of these drug products to ensure that they are being used appropriately and under the direct supervision of a qualified medical practitioner.

With the inherent and severe complications associated with topical ophthalmic anesthetic toxicity when used inappropriately, the expectation would be that these products should only be available with a physician's prescription.

Pharmacists dispensing these products have a professional obligation that these products are being used appropriately and under the supervision of an ophthalmologist. The consequences of inappropriate use are severe and/or catastrophic, as it can result in blindness. The side effects and potential for causing blindness would need to be explicitly indicated to the patient by the pharmacist if these products are dispensed.

For these reasons, repeated administration of ophthalmic anesthetics should be avoided and they should not be given to patients to take home for pain relief (6).

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