



Safety Information 003/14

The Risk of Toxicity from Topical Anaesthetic Products

18 September 2014

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Private Health Care

We recommend you also inform:

- Directors of Anaesthetics
- Directors of Pharmacy
- Drug and Therapeutics Committees
- Directors of Nursing and Midwifery

Expert Reference Group

Content reviewed by

- Clinical Excellence Commission
- NSW Therapeutic Advisory Group
- Medication Safety Expert Advisory Group

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This Safety Information Notice has been prepared to highlight the potential for patients to experience serious toxicity following application of topical anaesthetic products. These products frequently contain lignocaine or amethocaine and may also contain vasoconstrictors such as phenylephrine or adrenaline.

Lignocaine is used widely in clinical practice. Under normal conditions systemic absorption is generally insufficient to cause major toxicity. However, severe lignocaine toxicity has been reported and remains a possibility particularly in susceptible people. Toxic reactions can include central nervous system effects such as dizziness, confusion and loss of consciousness as well as cardiac effects including hypotension, bradycardia and cardiac arrest. Amethocaine is used in similar formulations for similar indications and has similar risks of toxicity.

Sympathomimetics, phenylephrine and adrenaline are frequently included in local anaesthetic products to cause local vasoconstriction, reducing systemic absorption of the local anaesthetic and prolonging its duration of action. Excessive topical application of phenylephrine has been associated with cardiovascular side effects, including myocardial infarction.

Factors contributing to Toxicity

High systemic absorption due to:

- Use of excessive quantities;
- Application to irritated or broken skin, or traumatised mucosa;
- Extended duration of use;
- Short intervals between application of doses;
- Application to large areas of the body; and
- Using occlusive dressings or wrappings on areas where lignocaine is applied.

Pre-existing susceptibility to toxicity from local anaesthetics due to:

- Cardiac disease
- Age (young and elderly)
- Debilitation

Steps to Minimise Risk

- Be aware of the possibility of systemic absorption and associated side effects when using topical anaesthesia.
- Review the site before applying topical anaesthetic products to ensure that all skin and mucous membranes are appropriately intact.
- Exercise care when local anaesthetics are used topically in children, and in the elderly, debilitated, or those with existing cardiac conditions.
- Use these products according to the approved product information or local protocols and guidelines as appropriate.

Recommended actions by Local Health Districts/ Networks.

1. Distribute this Safety Information Notice to all relevant clinical staff to ensure they are aware of the risks of systemic lignocaine toxicity following topical application.
2. Ensure that clinical staff have appropriate access to full and approved product information outlining the clinical indications and precautions for use of topical anaesthetic products.
3. Review use of topical anaesthetics in all procedural areas ensuring that written protocols for its use are available in these areas.



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Examples of Commonly Used Topical Products Containing Local Anaesthetics

- CoPhenylcaine Forte Spray (lignocaine 5% and phenylephrine 0.5% nasal spray)
- Xylocaine (various formulations: 2% viscous, 10% pump spray, 4% topical solution, 2% jelly, 5% ointment)
- EMLA (lignocaine 2.5%, prilocaine 2.5%) cream or patch
- LMX4 (lignocaine 4%) cream
- Ziagel (lignocaine 5%) dental gel
- Non-proprietary products obtained via contract manufacturing (for example, amethocaine 0.5% + lignocaine 4% + adrenaline 0.1%)

References/Other useful information can be found at:

1. Brosh-Nissimov, T. Ingbir, M. Weintal, I. Fried, M. Porat, R. Central nervous system toxicity following topical skin application of lidocaine. *Eur J Clin Pharmacol* (2004) 60: 683–684
2. Lidocaine (Lignocaine) In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.
3. Tetracaine (Amethocaine) In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.
4. Phenylephrine In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.
5. Local Anaesthetics: Adverse Effects Revised September 2007. ©Therapeutic Guidelines Ltd (etg35, November 2011)
6. US Food and Drug Administration, 2009. Public Health Advisory: Potential Hazards of Skin Products Containing Numbing Ingredients for Relieving Pain from Mammography and Other Medical Tests and Conditions.

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/PublicHealthAdvisories/ucm110625.htm>