Safety Information 003/20

The Risk of Toxicity from Topical Anaesthetic Products

22 May 2020

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

We recommend you also inform:

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

Expert Reference Group

Content reviewed by:

- Medication Safety Expert Advisory Committee
- Clinical Director, Emergency Care Institute

Clinical Excellence Commission

Tel: 02 9269 5500

Fax: 02 9269 5599

Email: CEC-MedicationSafety@health.nsw.gov.au

Internet Website: http://health.nsw.gov.au/sabs

Intranet Website: http://internal.health.nsw.gov.au/quality/sabs

Review date

May 2021

This Safety Information (SI) Notice updates and replaces the information within SI:003/14. It has been prepared to highlight the potential for patients to experience serious toxicity following application of topical anaesthetic products if used incorrectly. These products frequently contain lidocaine (lignocaine) or tetracaine (amethocaine) and may also contain vasoconstrictors such as phenylephrine or adrenaline (epinephrine).

Lidocaine (lignocaine) is used widely in clinical practice. 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. Tetracaine (amethocaine) is used in similar formulations for similar indications and has similar risks of toxicity.

Sympathomimetics, phenylephrine and adrenaline (epinephrine) 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.

Incorrect use contributing to Toxicity

When used as recommended, systemic absorption of these substances is minimal and major toxicity is avoided. **Severe toxicity however, has been reported when incorrect use results in high systemic absorption e.g. incorrectly applying lidocaine (lignocaine) spray directly to gauze or nasal packing.**

These products should be used only as recommended

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;
- Using occlusive dressings or wrappings on areas where lidocaine (lignocaine) is applied;
- Application to gauze or nasal packing.

Pre-existing susceptibility to toxicity from local anaesthetics due to cardiac disease, age (young and elderly), or 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 Drug and Therapeutics Committee-approved 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 lidocaine (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 and ensure that written protocols for use are available in all relevant areas.

The Risk of Toxicity from Topical Anaesthetic Products

22 May 2020

Examples of Commonly Used Topical Products Containing Local Anaesthetics

- CoPhenylcaine Forte Spray [lidocaine (lignocaine) 5% and phenylephrine 0.5% nasal spray]
- Xylocaine (various formulations: 2% viscous, 10% pump spray, 4% topical solution, 2% jelly, 5% ointment)
- EMLA [lidocaine (lignocaine) 2.5%, prilocaine 2.5%)] cream or patch
- LMX4 [lidocaine (lignocaine) 4%] cream
- Versatis [lidocaine (lignocaine) 5%] patch
- Ziagel [lidocaine (lignocaine) 5%] dental gel
- Non-proprietary products obtained via contract manufacturing [for example, tetracaine (amethocaine) 0.5% + lidocaine (lignocaine) 4% + adrenaline (epinephrine) 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 Published December 2019. ©Therapeutic Guidelines Ltd (eTG, March 2020)
6. Warren L, Pak A, Maniker R, Crowley M. Local anaesthetic systemic toxicity. UpToDate. 30 May 2019 (cited 22 April 2020)