



Povidone-Iodine (PVI) Use in NSW Hospitals

19 April 2017

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit
- Healthshare NSW

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Operating Theatres

We recommend you also inform:

- Operating Theatre Departments
- Directors of Operating Theatres
- Directors of Surgery
- Directors of Anesthetics
- Infection Prevention & Control Services
- Directors of Nursing & Midwifery
- Directors of Pharmacy
- Drug & Therapeutics Committees
- Directors Medical Imaging

Content reviewed by:

- Povidone-Iodine Working Party
- Healthcare Associated Infections Expert Advisory Committee
- Clinical Excellence Commission
- Agency for Clinical Innovation

Clinical Excellence Commission

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Review date

April 2019

Background

NSW public health facilities have reported internal usage of povidone-iodine (PVI) including but not limited to:

- intra-cavity lavage
- wound irrigation
- soaking or rinsing of implantable items e.g. breast implants, hernia/gynaecological mesh and central-venous access devices (CVAD) prior to insertion.

This is considered “off label” use and there is insufficient or low quality evidence to support these practices.

Concerns have been raised that:

- PVI is not being used according to the manufacturer's instructions and TGA registered indications. TGA registered indications are related to external use only, any uses outside the registered indications are considered ‘off-label’.
- Non-sterile formulations of PVI are being used ‘off-label’, increasing the risk of infection to patients.
- Some PVI solutions are not TGA registered as a pre-operative surgical antiseptic solution but are being used for this purpose.

PVI is known to be a broad spectrum antiseptic agent with activity against a wide range of bacteria, viruses, fungi, protozoa and spores. It is available in both sterile and non-sterile preparations. The intended use of povidone iodine should be assessed as to whether the need for sterile or non-sterile solution is required. The application of non-sterile solution as external skin antiseptics is acceptable practice. Caution is recommended if adding a non-sterile solution to an aseptic field for use during invasive procedures.

Recommendations

1. Povidone-iodine is for external use only
2. Povidone-iodine must be used as per the manufacturer's instructions and the Therapeutic Goods Administrations (TGA) - Australian Register of Therapeutic Goods (ARTG), refer to table on page 2 of this safety notice.
3. Povidone-iodine is registered as a medicine with the TGA; use outside of the registered indications is “off-label” and must be in accordance with [PD2016_033 Approval process of medicines for use in NSW public hospitals.](#)

Suggested actions by Local Health Districts/Networks

1. Distribute this safety notice to the appropriate areas for action.
2. Review for what purpose various PVI solutions are used by each health facility's perioperative unit and procedural areas.
3. Establish that only PVI solutions indicated for use as a preoperative skin antiseptic are used for pre-operative skin-antiseptics.
4. Establish the basis and use of sterile and non-sterile PVI solutions.
5. Ensure a system is in place to document actions taken.



Safety Notice 005/17

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There are currently a number of povidone-iodine solutions on contract with HealthShare NSW that are available to LHDs/SNHs via the OneLink Warehouse. These PVI products are registered by the TGA-ARTG for external use only, as displayed in the table.

Povidone-Iodine Solutions Available

ARTG No	ARTG Label	ARTG Specific Indication	Sterile or non-sterile	Pre-Operative Skin Antiseptic	Product Image
10796	POVIDONE-IODINE SOLUTION 10% w/v cutaneous solution. Bottle (100ml) . <i>Pfizer</i> .	A topical antiseptic for use as pre-operative skin antiseptic and for the treatment of minor cuts, abrasions and skin infections.	Non-sterile	Yes	
12643	POVIDONE-IODINE SOLUTION 10% w/v cutaneous solution. Steritube (30ml) . <i>Pfizer</i> .	A topical antiseptic for use as a pre-operative skin antiseptic and for the treatment of minor cuts, abrasions and skin infections.	Sterile	Yes	
21199	Herron Riodine Antiseptic Solution Povidone-Iodine 100mg/mL. Bottle (100ml) . <i>Perrigo</i> .	For antiseptics of minor cuts, wounds and abrasions and treatment of minor skin infections.	Non-sterile	Not Registered	
29562	BETADINE ANTISEPTIC SOLUTION povidone-iodine 100mg/mL paint. Bottle (100ml) . <i>Sanofi</i>	For minor cuts and abrasions and the treatment of minor skin infections. For antiseptics of minor cuts and abrasions.	Non-sterile	Not Registered	
12645	POVIDONE-IODINE SOLUTION 10%w/v cutaneous solution. Tube (25ml) . <i>Pfizer</i>	A topical antiseptic for use as a pre-operative skin antiseptic and for the treatment of minor cuts, abrasions and skin infections	Non-sterile	Yes	