17 June 2022

LINK
A CLINIGEN COMPANY

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RE: Discontinuation of POVIDONE-IODINE SOLUTION 10%w/v cutaneous solution ampoule and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the discontinuation of Australian registered **POVIDONE-IODINE SOLUTION 10%w/v cutaneous solution ampoule *(Aust R* 12643)**, LINK has arranged the supply of an alternative product, ***Aplicare 10% Sterile Povidone-Iodine Liquid Pouch*** registered and marketed in the United States of America.

Aplicare 10% Sterile Povidone-Iodine Liquid Pouch is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **30 June 2023.**

Aplicare 10% Sterile Povidone-Iodine Liquid Pouch are indicated for:

> *Topical antiseptic for use as a pre-operative skin antiseptic and for the treatment of minor cuts, abrasions and skin infections.*

The s19A approved *USA* product is identical in active ingredient and strength to the Australian registered product. The s19A product is a 22.5mL sterile pouch. The two products differ in their storage conditions and excipient ingredients. These differences are noted below:

	ARTG product (POVIDONE-IODINE SOLUTION 10%w/v cutaneous solution ampoule**)**	**S19A product (**Aplicare 10% Sterile Povidone-Iodine Liquid Pouch**.)**
Storage	Store below 25°c	Store at room temperature. Avoid excessive heat.
Excipients	citric acid dibasic sodium phosphate macrogol 400 nonoxinol 10 water for injections	Citric Acid disodium phosphate Nonoxynol-9 Sodium Hydroxide Water

Aplicare 10% Sterile Povidone-Iodine Liquid Pouch are registered in the ***USA*** with the outer package in English. The active ingredient, strength and dosage form included on the sterile pack and pouch label are in English.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with ***Aplicare 10% Sterile Povidone-Iodine Liquid Pouch*** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the discontinuation of the Australian registered **POVIDONE-IODINE SOLUTION 10%w/v cutaneous solution ampoule *(Aust R* 12643).**

Yours sincerely,

C Griffin

Charlotte Griffin

Medicine Access Associate