16th August 2022

Dear Healthcare Professional,

Availability of DUKAL Povidone-Iodine USP 10% sterile solution pouch - under alternative supply arrangement of Section 19A of the Therapeutic Goods Act.

Due to the discontinuation of the Australian registered POVIDONE-IODINE SOLUTION 10%w/v cutaneous solution ampoule, 30mL ARTG 12643, Reach Pharmaceuticals has arranged the supply of the alternative product called **DUKAL Povidone-Iodine USP 10% sterile solution pouch** registered and marketed in the United States.

DUKAL Povidone-Iodine USP 10% sterile solution 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 30th June 2024.

DUKAL Povidone-Iodine USP 10% sterile solution pouch is indicated for:

A topical antiseptic for use as a pre-operative skin antiseptic.

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 (**DUKAL Povidone-Iodine USP 10% sterile solution 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 Glycerin Sodium Hydroxide Potassium Iodide Alkyl Glucoside Nonoxynol-10 Hydroxyethyl Cellulose Purified Water

DUKAL Povidone-Iodine USP 10% sterile solution pouch are registered in the **USA** with the outer package in English. The active ingredient, strength and dosage form included on the 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 **DUKAL Povidone-Iodine USP 10% sterile solution pouch** should be reported by healthcare professionals and patients to our Medical Information. This information can also be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Reach Pharmaceuticals Medical Information can be contacted by phone on 1800 505 306 or via email at medical@reach-pharma.com

For sales related enquiries, please contact us on sales@reach-pharma.com or call 0422 429 648.

We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

Yours sincerely,

Reach Pharmaceuticals Pty Ltd