

PRODUCT INFORMATION SHEET
SILKEN® - SILICONE STOMA GEL
REF : TR1070

Intended use:
 Protective gel for use around stomas & fistulas.

Method of administration:
 Silken® stoma gel is used to fill uneven skin surfaces. Ensure the skin is clean and dry. Squeeze the silicone gel from the base of the tube to fill depressions and skin contours. If required, spread the gel with a wetted finger or spatula. Silken® stoma gel will cure underneath the wafer / base plate during normal wear time.

Features & benefits	One piece removal	Atraumatic removal	Cures to form a soft gel	Non-absorbent to faeces and urine
	Leaves no residue when fully cured	Less skin irritation	Remains soft and flexible to ensure comfort	More hygienic than hydrocolloid products and Promotes healthier skin

Product form:
 A silicone stoma gel available as a 60gm tube



Packaging information:	1 ⁰	295 micron Laminated tube	60g / tube
	2 ⁰	Inner carton	1 tube / carton
	3 ⁰	Corrugated outer box.	24 cartons / box
Instructions for use: Instructions for use supplied in each carton. Multilingual presentation (13 Languages).			
Regulatory information:	Legal manufacturer:	Trio Healthcare Ltd Skipton, United Kingdom. Telephone: +44 (0) 1756 700599 Quality Management System Registration ISO13485:2003 – Certificate No.: MD526018 British Standards Institution.	
	Classification:	Class I non-sterile medical device. MDD93/42/EEC Annex IX - Rule 1.	
	Biological safety evaluation:	The product meets the requirements for biological safety in accordance with international standard EN ISO 10993. Independent biological safety evaluations and testing having been undertaken. <u>References:</u> Expert evaluation on the biological safety of Trio Healthcare Ltd silicone stoma gel product – RTA . [PCL-B-027] Harlan Laboratories Study # 41403904	
	Shelf-life:	18 months. Expiry date printed into tube seal.	
	Special storage conditions:	This product should not be stored above 50 ⁰ C. See accompanying instruction for use.	
	First placed on market:	July 2014	
Environmental information:	Special precautions for disposal after use	None. Suitable for hospital / household waste streams.	
Web site information: www.TrioOstomyCare.com			

DATE OF ISSUE: January 2015

Issue: First issue

Change History

DATE	REASON
Jan 2015	First issue.