



Technical Data Sheet

Product: Loris Alcohol Swabs, Sterile

NPN 80063395 (Canada)

Product Packaging

Product Code: 104-03

Pouch size: 50 mm x 50 mm

Open wipe: 65 mm x 30 mm (nominal)

Closed wipe: 32 mm x 30 mm (nominal)

Seals dimensions: min. 3 mm all around

Solution content: Minimum 0.35 mL/pouch

Packaging Format: 200 pads / display box & 20 display boxes / corrugate

Corrugates per skid: 144

Product Label

Use: Antiseptic topical skin cleanser prior to injection. Helps reduce bacteria that can potentially cause infection. For occasional use, as needed.

Directions: Apply a wipe directly to the skin.

Cautions and warnings: For external use only. Avoid contact with eyes. If contact occurs, flush eyes with water. Discontinue use and consult a health care practitioner if irritation develops. Store in a cool dry place and away from sources of ignition. **Single-Use only. Do not use if package is broken or open.**

NPN 80063395	PROD.#: 104-03
LORIS TM _{MD}	
Serviette Stérile d'Alcool Isopropylique Antiseptique	
Sterile Antiseptic Isopropyl Alcohol Wipe	
LERNAPHARM (LORIS) INC., 2323 HALPERN, VILLE ST-LAURENT QUÉBEC, CANADA H4S 1S3 MADE IN CANADA	
4	<p>Active ingredient: Isopropyl Alcohol 70% v/v. Uses: Antiseptic topical skin cleanser prior to injection. Helps reduce bacteria that potentially can cause infection. For occasional use, as needed. Directions: Apply a wipe directly to the skin. Warnings: For external use only. Avoid contact with eyes. If contact occurs, flush eyes with water. Discontinue use and consult a healthcare practitioner if irritation develops. Use with caution in children. Do not ingest. Flammable. Keep away from open flame and sources of heat. Do not use if package is open or broken. Single use only. Not intended for use as a hand sanitizer (handrub). Store at room temperature between 15-30°C. Inactive ingredients: Purified Water</p> <p>Ingrédient actif: Alcool isopropylique 70% v/v. Usage: Nettoyant antiseptique topique avant l'injection. Aide à réduire les bactéries qui potentiellement peuvent causer l'infection. Pour usage occasionnel, au besoin. Directives: Appliquer un tampon directement sur la peau. Avertissements: Pour usage externe seulement. Éviter le contact avec les yeux. En cas de contact, rincer les yeux avec de l'eau. Cesser l'utilisation et consulter un praticien de soin de santé en cas d'irritation. Utiliser avec précaution avec les enfants. Ne pas ingérer. Inflammable. Garder loin du feu et des sources de chaleur. Ne pas utiliser si le sachet est ouvert ou brisé. Pour usage unique seulement. Non destiné à être utilisé comme désinfectant pour les mains. Entreposer à température ambiante entre 15-30°C. Ingrédients inactifs: Eau purifiée</p>
LOT #:	EXP:



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Quality Controls on Finished Products

Test	Method	Specification
Fill volume	S-MAN-003	Minimum 0.35 mL
Seal Integrity	S-MAN-013	No leaks found in bundle of pouches when hardly squeezed between two plates

Chemical / Biological Analysis

Test*	Method	Specification
Appearance	TL-S-QUA-010	Transparent, clear, colorless and clean liquid with a characteristic odor
Assay of Isopropyl Alcohol	TL-S-QUA-023	68.0%-72.0%
Certificate of gamma-irradiation, irradiation dose	Visual	18.2 kGy – 45 kGy
Total Aerobic Microbial Count (TAMC)	TL-S-QUA-028	< 10 cfu/ml
Total Combined Yeast and Mold Count (TYMC)	TL-S-QUA-028	< 2 cfu/ml
S. aureus	TL-S-QUA-053	Absence
P. aeruginosa	TL-S-QUA-053	Absence
B. cepacia	TL-S-QUA-053	Absence

*Tests are made on the bulk solution