

HR® Lubricating Jelly and HR® Lubricating Jelly 2X Instructions for Use

MANUFACTURER:

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PRODUCTS

REF	Product Description	Sterile	Use	Package Size
201	HR® Lubricating Jelly 113g (4oz.) Flip-Top Tube - Sterile	Yes	Multi-Use	113g
203	HR® Lubricating Jelly 56.5g (2oz.) Flip-Top Tube - Sterile	Yes	Multi-Use	56.7g
205	HR® Lubricating Jelly 36g (1.25oz.) OneShot® - Sterile	Yes	Single-Use	36g
205ST	HR® Lubricating Jelly 36g (1.25oz.) OneShot® SafeWrap® - Sterile	Yes	Single-Use	36g
206	HR® Lubricating Jelly 10ml Pre-Filled Syringe - Sterile	Yes	Single-Use	10g
207	HR® Lubricating Jelly 3g OneShot® - Sterile	Yes	Single-Use	3g
208	HR® Lubricating Jelly 3g OneShot® CarePac® - Sterile	Yes	Single-Use	3g
209	HR® Lubricating Jelly 5g OneShot® - Sterile	Yes	Single-Use	5g
210	HR® Lubricating Jelly 2X 60g (2.1oz.) Flip-Top Tube - Sterile	Yes	Multi-Use	60g
211	HR® Lubricating Jelly 2X 36g (1.25oz.) OneShot® - Sterile	Yes	Single-Use	36g

INDICATIONS FOR USE

HR® Lubricating Jelly is a sterile gel intended to facilitate entry of a diagnostic or therapeutic device into a body orifice by reducing friction between the device and body; it is not dedicated to a particular type of the anatomy. After application, the device cannot be reused.

DESCRIPTION

HR® Lubricating Jelly is water-soluble, stable, non-greasy and spreads evenly. It is widely used in hospitals and physicians' offices...ideal for lubricating rubber products...rectal thermometers...rectal and vaginal nozzles for infants and adults.

DEFINITIONS

SafeWrap®—A sterile pouch in which the individual lubricating jelly packet is placed. *SafeWrap* is a registered trademark of HR Pharmaceuticals, Inc., its subsidiaries or divisions.

OneShot®—A single-use style packaging designed to be thrown out after the lubricating jelly is dispensed.

PRODUCT FEATURES

Water-Soluble
Unscented
Greaseless
Latex Free
Sterile
BPOC Compliant
Kosher

CONTRAINDICATIONS

Sensitivity to ingredients. Reference SDS.

WARNINGS AND PRECAUTIONS

Do not use product beyond labeled expiration date as sterility and performance cannot be guaranteed.

Re-use of the HR® Lubricating Jelly Product (REF #'s 205, 205ST, 207, 208, 209, 211) could result in cross-contamination, risks of infection, or adverse reaction for the patient.

A very small percentage of men and women may be sensitive to one or more of the ingredients in this lubricant. If irritation is experienced, discontinue use and notify a physician. Keep out of reach of children.

If irritation occurs, discontinue use and consult a physician.

Do not use product if package is damaged or opened.

Do not use if seal under cap is broken or missing (REF#'s 201, 203, 210).

Use of a lubricating jelly for a task other than that for which it is intended could result in risk to the patient or one which provides an unsatisfactory performance.

PRE-USE, HANDLING, AND INSPECTION

The product must be thoroughly inspected upon receipt and prior to use to assure packaging is not damaged or defective. If any product damage or leakage is identified, the product should be discarded.

INSTRUCTIONS FOR USE

1. **HR® Lubricating Jelly OneShot® SafeWrap® (REF # 205ST)**
 - a) Sanitize exterior of SafeWrap® pouch prior to introduction to sterile environment.
 - b) Remove the SafeWrap® outer pouch and place the HR® Lubricating Jelly packet on the sterile tray.
 - c) Apply an amount of HR® Lubricating Jelly directly to the patient or instrument as needed.
 - d) Discard package after use.











2. **HR® Lubricating Jelly OneShot® (REF #'s 206, 207, 208, 209, 205, 211)**
 - a) Apply an amount of HR® Lubricating Jelly directly to the patient or instrument as needed.
 - b) Discard package after use.


3. **HR® Lubricating Jelly Flip-Top Tube (REF #'s 201, 210, 203)**
 - a) Sanitize cap and tip prior to opening. Remove tamper-evident seal.
 - b) Flip cap to open.
 - c) Apply an amount of HR® Lubricating Jelly directly to the patient or instrument as needed.

RECOMMENDED STORAGE CONDITIONS


Store in a clean, dry place at room temperature (15°-30°C or 59°-86°F).

GLOSSARY OF SYMBOLS


ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements			
Symbol	Reference	Title of Symbol	Description or Meaning
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process
	5.1.5	Batch number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.4	Use-by date	Indicates the date after which the medical device is not be used.
	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.

Symbol	Reference	Title of Symbol	Description or Meaning
	5.4.5 and Annex B.2 and Guidance for Industry and US Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex; Issued on December 2, 2014	Not made with natural rubber latex	Indicates that neither the medical device nor the packaging of the medical device contains the presence of natural rubber latex.


Union of Orthodox Jewish Congregations of America (the “Orthodox Union”) certification requirements for kosher products

Symbol	Reference	Title of Symbol	Description or Meaning
	Kosher Requirements per Union of Orthodox Jewish Congregations of America	Certified Kosher	Certified Kosher per the Union of Orthodox Jewish Congregations of America as Pareve (contains neither milk or meat ingredients)

Islamic Food and Nutrition Council of America certification requirements for Halal products

Symbol	Reference	Title of Symbol	Description or Meaning
	Halal Requirements per Islamic Food and Nutrition Council of America	Halal Certified	Certified Halal per the Islamic Food and Nutrition Council of America

Federal Trade Commission Guidance on Compliance with “Made in USA”

Symbol	Reference	Title of Symbol	Description or Meaning
	N/A	Made in USA	All or virtually all significant parts and processing of this product are of U.S. origin.