

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

MANUFACTURER:

HR Pharmaceuticals Inc.
 2600 Eastern Boulevard, Suite 201
 York, PA 17402 USA
 (877)252-1110
www.hrpharma.com

PRODUCTS

REF	Product Description	Sterile	Use	Package Size
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
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
211	HR Lubricating Jelly 2X 36g (1.25oz.) OneShot® - Sterile	Yes	Single-Use	36g
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
210	HR Lubricating Jelly 2X 60g (2.1oz.) Flip-Top Tube - Sterile	Yes	Multi-Use	60g

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 207, 208, 209, 205, 205ST, 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, 210, 203).

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.

STORAGE CONDITIONS

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

GLOSSARY OF SYMBOLS

SYMBOL	MEANING
	Catalog number
	Manufacturer
	Do Not Use if Opened or Damaged
	Sterile
	Do Not Re-Use/Single-Use Only
	Consult Instructions for Use
	Warning
	Lot Number
	Expiration Date
	Store between temperature limitations
	Not made with natural rubber latex
	Kosher Certified
	Halal Certified
	Made In USA