

John Troup

05/19/25

BabyDance®

Fertility Lubricant

Instructions

Package Contents

1 multiuse tube (40g/1.4 oz.) for external and internal use

Indications for Use

BabyDance Fertility Lubricant is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. BabyDance Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying-to-conceive couples. BabyDance Fertility Lubricant is compatible with natural rubber latex and polyurethane condoms.

BabyDance Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.

Directions

To supplement natural lubrication, BabyDance Fertility Lubricant is designed to be applied externally and/or internally to vaginal tissues prior to intercourse. Most women apply the lubricant before intimacy begins, but it can be applied any time prior to or during intercourse to enhance the comfort of intimacy.

To use BabyDance Fertility Lubricant, remove the protective seal from the top of the tube. Squeeze lubricant into your hand and apply to your vaginal tissues and/or your partner's penis. Reapply as needed.

Using BabyDance With Condoms

To use with nonlubricated or polyurethane condoms, squeeze BabyDance into your hand and apply to the outer condom surface. For easier placement of the condom, squeeze a small amount of BabyDance onto your fingertips and apply to the penis prior to putting on the condom.

Professional Use in the Clinic

BabyDance Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine. Prior to device insertion, BabyDance Fertility Lubricant can be applied directly to the device from the tube or applied to the vaginal tissues and/or penis for lubrication.

BabyDance Fertility Lubricant is not a sterile product and should not be used if sterile product is required.

Ingredients

Purified water, cetyl hydroxyethylcellulose, hypromellose, carbomer homopolymer type B, sodium phosphate, potassium phosphate, sodium chloride, raspberry-derived xylose, sodium hydroxide, phenethyl alcohol, caprylyl glycol, Salvia sclarea (clary sage)

Caution

If irritation occurs, discontinue product immediately. If irritation persists, consult your healthcare provider.

FairhavenHealth

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Quality Assurance

Each lot of BabyDance Fertility Lubricant is tested to ensure the following:

Physical Specification/Test	Ranges/Specifications
Color/appearance	Opaque
Odor	Slight rose and sage odor
pH @ 25 °C	6.8 to 7.2
Osmolality	260 to 370 mOsmo/kg
Apparent Viscosity	2,000 to 14,000 cps
Total Aerobic Microbial Count (TAMC) per USP <61>	< 100 cfu/g
Total Yeast and Mold Count (TYMC) per USP <61>	< 10 cfu/g
Pathogens (<i>Pseudomonas aeruginosa</i> , <i>Escherichia Coli</i> , <i>Salmonella sp.</i> , <i>Candida albicans</i>) per USP <62>	Absent
Endotoxin by endotoxin methodology per USP <85>	≤ 0.5 EU/ml
Biocompatibility by Mouse Embryo Assay	Using 1-cell MEA exposed to 10% solution for 30 min. ≥ 80% expanded blastocysts at 96 hrs.
Biocompatibility by Sperm Motility	Sperm motility following 30 min. incubation with 10% diluted lubricant solution equals ≥ 80% of sperm in control medium

Results of the specification testing are reported on a lot-specific Certificate of Analysis, which is available upon request.

Important

Close cap tightly between each use. Store at 36–86 °F (2–30 °C). No patient data are available regarding pregnancies or birth outcomes in women using this product.

Some women feel a warming sensation in the vagina when first using BabyDance Fertility Lubricant. This sensation may be due to the pH balancing of vaginal tissues in preparation for ovulation and generally decreases with subsequent use.

Warnings

BabyDance is not a contraceptive. **BabyDance Fertility Lubricant does not harm sperm.**

Do not use if quality seal on the tube is broken; instead return BabyDance Fertility Lubricant to the place of purchase.

Do not use BabyDance Fertility Lubricant if active infection or vaginal trauma is present.

DO NOT USE AFTER EXPIRATION DATE.

Learn more at [fairhavenhealth.com](https://www.fairhavenhealth.com) or 800.367.2837.

Made in the USA for Fairhaven Health, LLC
45 Kenneth Dooley Drive
Middletown, CT 06457
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Final Audit Report

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