



ALPHA DELAY WIPES™
With 4% Benzocaine

Instructions for Use

PRINCIPLE AND INTENDED USE

Alpha Delay Wipes™ with 4% Benzocaine device is intended for the desensitization of the male genitalia to reduce overstimulation without eliminating sensation altogether to ensure longer lasting sex

COMPOSITION

Alpha Delay Wipes™ contains:

- 4% Benzocaine (Active Ingredient)
- Ethyl Alcohol (SDA 40B), Propylene Glycol, Purified Water (Inactive Ingredients)

CLINICAL INVESTIGATIONS TO DEMONSTRATE CONFORMITY TO THE SAFETY AND PERFORMANCE CRITERIA OF THE MEDICAL DEVICE

Limited studies have been conducted in reference to the Journal of Urology **“RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFICACY, SAFETY, AND TOLERABILITY OF BENZOCAINE WIPES IN SUBJECTS WITH PREMATURE EJACULATION”** Shabsigh et al., (2017)

“This randomized, placebo controlled clinical trial with crossover design showed that Benzocaine wipes applied topically to the penis prior to sexual intercourse had a statistically significant prolongation of time to ejaculation, a clinically meaningful benefit, in the treatment of premature ejaculation. Furthermore, Benzocaine wipes were well tolerated by the subjects and no evidence of transference to their female partners.” Shabsigh et al., (2017)

STORAGE AND HANDLING

- The device is to be stored in a cool and dry place
- The storage temperature should be under 25°C

PRECAUTIONS

This device contains a scheduled substance which is benzocaine a numbing substance intended to prolong ejaculation.

Premature ejaculation may be due to a medical condition that requires medical attention, the product is not intended to cure premature ejaculation. The device should be used as per the instructions.

The following points below are the precautionary measures that are to be taken when using the product:

Do not use the device if you are allergic to Benzocaine. Benzocaine can cause a serious condition in which the amount of oxygen carried through the blood is greatly reduced (methemoglobinemia).

When using this product avoid contact with the eyes. If contact with eyes occur, flush the eye with plenty of water and consult a doctor.

The device is not reusable as one wipe is intended for a single use.

Do not use the device if the packaging has been tampered with.

Do not use the device post the expiry date on the packaging.

Do not use the product if you are below the age of 18.

The device is not intended for oral use and if swallowed immediately seek medical attention or contact the poison control unit.

Discontinue the use of the product and consult a medical practitioner if you develop the following:

A rash, irritation, burning, or itching are an indication of an allergic reaction to Benzocaine.

WASTE DISPOSAL

Alpha wet wipes do not cause any microbial hazards or physical hazards, to eliminate the occurrence of environmental hazards, the wipes should not be flushed but rather disposed in a waste and/or refuge bin.









INSTRUCTIONS FOR USE

The device does not require any calibration, sterilization or installation. No training or special facilities are required; the device is intended to be used five minutes prior to sexual intercourse.

Apply a small amount to head and shaft of penis before intercourse or use as directed by a doctor. Allow at least five minutes to dry. Wash product off after intercourse.

The device is not meant to be used in conjunction with any consumable components. Consultation with a health professional is not a requirement to use this device.

INDEX OF SYMBOLS

	Consult instructions for use		Use by		0123456789		Do not reuse
	Non sterile		Do not use if package is damaged		Temperature limitations		Manufacturing date



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Number:
Effective Date: