MASSAGE MEN GEL MAX TIME- benzocaine gel
Valley of the Sun Cosmetics LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Massage Men Gel Max Time

Active Ingredient

Benzocaine 7%

Purpose

Male Genital Desensitizer

Uses

- helps in the prevention of premature ejaculation
- helps in temporarily prolonging the time until ejaculation

Warning

For external use only

When using this product

Avoid contact with eyes

Stop use and ask doctor

- Premature ejaculation may be due to a condition requiring medical supervision. If this product, used as directed, does not provide relief, discontinue use and consult a doctor.
- If you or your partner develop rash or irritation, such as burning or itching, discontinue use. If symptoms persist, consult a doctor.

If pregnant or breast feeding

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children

If swallowed, get medical help, or contact a poison control center right away.

Directions

- apply a small amount to the head and shaft of the penis before intercourse or use as directed by a doctor. Wash product off after intercourse.
- use only on intact, non-inflamed skin
- allow gel to dry prior to intercourse
- not suitable for oral use
- use as directed, not more than four times per day

Other information

- Store between 20-25°C (68-77°F)
- Compatible with latex condoms
- Children resistant closure. Instructions for opening are included in the leaflet
- Read the enclosed leaflet to achieve best results

Inactive Ingredients

Water (aqua), alcohol denatured, propylene glycol, disodium EDTA, carbomer, ginkgo biloba (ginkgo) extract, sodium hydroxide

Package Label

06-29-2021

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MASSAGE MEN GEL MAX TIME

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76523-068
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GINKGO (UNII: 19FUJ2C58T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color		**Score**	
Shape	ROUND (Round bottle)	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76523-068-15	15 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	07/02/2021	

Labeler - Valley of the Sun Cosmetics LLC (176470664)

Registrant - Valley of the Sun Cosmetics LLC (176470664)

Establishment

Name	Address	ID/FEI	Business Operations

Valley of the Sun Cosmetics LLC		176470664	manufacture(76523-068)