MASSAGE MEN GEL MAX SIZE- 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 Size

Active Ingredient

Benzocaine 5%

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 the 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 breastfeeding

If pregnant or breastfeeding, 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, eurycoma longifolia (long jack) root extract, sodium hydroxide

Package Label

06-29-2021





06-29-2021



MASSAGE MEN GEL MAX SIZE

benzocaine gel

	ormation						
Product Type		HUMAN OTC DRUG	Item Code	ode (Source) NDC:76523-06			
Route of Admi	nistration	TOPICAL					
A ativa Inawa		Maiaha					
Active Ingree		-				··	
	•	ient Name BENZOCAINE - UNII:U3RSY48JW5)		Basis of Strength		Strength	
BENZOCAINE (UI	NII: U3K5148JVV5)	(BENZ OCAINE - UNII:U3RS	148JVVD)	BENZOCAINE		5 g in 100 g	
Inactive Ingr	edients						
Ingredient Name						Strength	
PROPANEDIOL (U	JNII: 5965N8W857	-)					
EDETATE DISOD	IUM (UNII: 7FLD9	1C86K)					
CARBOMER 940	· · · · · · · · · · · · · · · · · · ·						
		(UNII: 43B8E2HG8B)					
SODIUM HYDRO	XIDE (UNII: 55X04	4QC32I)					
WATER (UNII: 059	QF0KO0R)						
ALCOHOL (UNII: 3	3K9958V90M)						
Product Cha	racteristics						
Color			S	core			
Shape	ROUND (Round Bottle)	S	Size			
Flavor			li	mprint Code			
Contains							
Packaging						leation For	
	Р	ackage Description	r	Aarketing Start Date	Mar	Date	
# Item Code		E, DISPENSING; Type 0: N	lot a		Mar	keting End Date	
# Item Code 1 NDC:76523-	15 g in 1 BOTTL	E, DISPENSING; Type 0: N	lot a	Date	Mar	-	
 # Item Code 1 NDC:76523- 063-15 Marketing 	15 g in 1 BOTTL Combination Pro	E, DISPENSING; Type 0: Noduct	lot a 0	Date	Mar	-	
# Item Code 1 NDC:76523- 063-15 Marketing Category	15 g in 1 BOTTL Combination Pro Informat Applica	E, DISPENSING; Type 0: Noduct	lot a 01	Date 7/01/2021 arketing Start Date		-	
1 NDC:76523- 063-15 Marketing Marketing	15 g in 1 BOTTL Combination Pro Informat Applica	E, DISPENSING; Type 0: Noduct	lot a 01	Date 7/01/2021 arketing Start		Date keting End	

Labeler - Valley of the Sun Cosmetics LLC (176470664)

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Registrant - Valley of the Sun Cosmetics LLC (176470664)									
Establishment									
Name	Address	ID/FEI	Business Operations						

Valley of the Sun Cosmetics LLC 176470664 manufacture(76523-063)	
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Revised: 7/2021

Valley of the Sun Cosmetics LLC