

**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.*

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**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.





06-29-2021



## MASSAGE MEN GEL MAX SIZE

benzocaine gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76523-063
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>EURYCOMA LONGIFOLIA ROOT</b> (UNII: 43B8E2HG8B)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	ROUND (Round Bottle)	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76523-063-15	15 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/01/2021	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part348	07/01/2021	

**Labeler** - Valley of the Sun Cosmetics LLC (176470664)

**Registrant** - Valley of the Sun Cosmetics LLC (176470664)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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Valley of the Sun Cosmetics LLC

176470664

manufacture(76523-063)

Revised: 7/2021

Valley of the Sun Cosmetics LLC