MASSAGE MEN GEL MAX POWER- 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 Power

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 supervion. If this
 product, used as directed, does not provide relief, discontinue use and consult a
 doctor.
- If you or your partner develop a 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 resistent 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, wthania somnifera (ashwagandha) root extract, sodium hydroxide

Package Label

97.28 mm

| Direction Continue | apply a small amount to the head and shaft of the period period of a small period of the period of a small period of the period of a small period of the period of th



MASSAGE MEN GEL MAX POWER

benzocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76523-062

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48IW5) (BENZOCAINE - UNII:U3RSY48IW5)	BENZOCAINE	5 g in 100 g

Inactive Ingredients

mactive migredients					
Ingredient Name	Strength				
WITHANIA SOMNIFERA ROOT (UNII: V038D626IF)					
CARBOMER 940 (UNII: 4Q93RCW27E)					
PROPANEDIOL (UNII: 5965N8W85T)					
WATER (UNII: 059QF0KO0R)					
SODIUM HYDROXIDE (UNII: 55X04QC32I)					
ALCOHOL (UNII: 3K9958V90M)					
EDETATE DISODIUM (UNII: 7FLD91C86K)					

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:76523-062-15	15 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/01/2021	

Marketing Information

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

Labeler - Valley of the Sun Cosmetics LLC (176470664)

Registrant - Valley of the Sun Cosmetics LLC (176470664)

Esta	h	lici	h	m	0	nt
ESLA	U	115			e	

Name	Address	ID/FEI	Business Operations

Valley of the Sun Cosmetics LLC	176470664	manufacture(76523-062)

Revised: 7/2021

Valley of the Sun Cosmetics LLC