#### SALINE- saline spray Healthlife of USA

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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#### Saline Nasal Spray

**Drug Facts** 

**Active Ingredients** 

Sodium Chloride 0.65%

## Purpose

For allergies: cold, flu, sinusitis, rhinitis and dry irritated nasal passages

## Ingredients

A solution of sodium chloride 0.65% in purified water (USP), made isotonic with sodium phosphate dibasic and sodium phosphate monobasic, with benzyl alcohol and benzalkonium chloride as preservatives.

## Uses

for dry nasal membranes squeeze twice in each nostril as needed.

## Directions

upright delivers as a spray, horizontally as a stream, upside down as a drop.

## Warnings

**If pregnant or breast-feeding,** Dask a healthcare professional before use. Use of this container by more than one person may spread infection.

## Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

## Questions or comments?

Call 1-844-832-1138

\*This product is not manufactured or distributed by Valeant Consumer Products, Distributors of Ocean Saline Nasal Spray.

## Saline Nasal Spray

Distributed by:

Healthlife of USA 1600 Hart Street, Rahway, NJ 07065

www.healthlifeofusa.com

HealthL*fe of USA	T IF IISSING	55% in sic, with rvatives.	n each	ontally	Ital		ant spray			
Compare to ingredient of Ocean®*	TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF Safety seal over the CAP is broken or missing	Ingredients A solution of sodium chloride 0.65% in purified water (USP), made isotonic with sodium shosphate dibasic and sodium phosphate monobasic, with perzyl alcohol and benzalkonium chloride as preservatives.	For dry nasal membranes squeeze twice in each as needed.	spray, horizontally	Trifings gnant or breast teeding, ask a health care gnoved before use. Use of this container by than one person may spread infection. out of reach of children. In case of accidental tion, get medical help or contact a Poison ol Center right away.		Juestions or comments? 1-844-832-1138 This product is not manufactured or distributed by Valeant Consumer Products, distributors of Ocean Saline Nasal Spray	K35021	e	
Saline Nasal Spray	USE THIS AP IS BRO	of sodium sotonic with m phospha ium chlorid	ranes sque	_	tding, ask a health care Use of this container by ay spread infection. Idren. In case of accide th or contact a Poison <i>V</i> .	A 07065	1-844-832-1138 factured or distrib butors of Ocean S		4	
Helps to moisturize dry and irritated nasal passage from conditions like allergies, cold, flu,	T: DO NOT	A solution P), made is and sodiu benzalkon	sal memb	upright delivers ide down as a d	<b>Igs</b> <b>it or breast feeding</b> , all before use. Use c one person may sp of <b>reach of children</b> get medical help or inter right away.	thLife of USA Rahway, NJ 07065 com	ents? 1-844 manufactur distributors		000	
sinusitis and rhinitis. • Safe for Frequent, Daily Nasal Care • Natural, Non-Medicated Relief	r seal ov	Ingredients A solution of sodium chloride ( purified water (USP), made isotonic with sodium phosphate dibasic and sodium phosphate monol benzyl alcohol and benzalkonium chloride as pre-	USE For dry na nostril as needed.	<b>Directions</b> upright delivers as a is a stream, upside down as a drop.	Warnings If pregnant or breast feeding, ask a health care professional before use. Use of this container by more than one person may spread infection. Keep out of reach of children. In case of accide ngestion, get medical help or contact a Poison Control Center right away.	Distributed by: HealthLife of 1600 Hart Street, I Rahway, www.healthlifeofusa.com	<b>Questions or comments?</b> This product is not manu Consumer Products, distri		50565	
	TAMPE	Ingre purified phosph benzyl a	<b>Use</b> nostril	<b>Direc</b> as a str	Warnin If pregnan profession more than Keep out ( ingestion, Control Ce	Distribut 1600 Ha	Consum		8 Lot#	Exp.

SALINE						
aline spray						
Product Informa	tion					
Product T ype		HUMAN OTC DRUG	Item Code (Sour	·ce)	NDC:69	9517-609
Route of Administra	ntion	NASAL				
Active Ingredien	t/Active Moi	ety				
Ingredient Name Basis of Streng					ength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) SODIUM CHLORIDE					RIDE	6.5 mg in 1 mL
Inactive Ingredie	ents					
Inactive Ingredie	ents	Ingredient Name				Strength
		•				Strength
SO DIUM PHO SPHAT	<b>E, DIBASIC</b> (UNI	I: GR686LBA74)				Strength
SO DIUM PHO SPHAT SO DIUM PHO SPHAT	E, DIBASIC (UNI E, MONOBASIC	I: GR686LBA74) (UNII: 3980JIH2SW)				Strength
SO DIUM PHO SPHAT SO DIUM PHO SPHAT BENZYL ALCOHOL	<b>E, DIBASIC</b> (UNI <b>E, MO NO BASIC</b> (UNII: LKG8494V	I: GR686LBA74) (UNII: 3980JIH2SW) VBH)				Strength
SO DIUM PHO SPHAT SO DIUM PHO SPHAT BENZYL ALCOHOL	<b>E, DIBASIC</b> (UNI <b>E, MO NO BASIC</b> (UNII: LKG8494V	I: GR686LBA74) (UNII: 3980JIH2SW) VBH)				Strength
Inactive Ingredie sodium phosphat sodium phosphat benzyl alcohol benzalkonium ch	<b>E, DIBASIC</b> (UNI <b>E, MO NO BASIC</b> (UNII: LKG8494V	I: GR686LBA74) (UNII: 3980JIH2SW) VBH)				Strength
SO DIUM PHO SPHAT SO DIUM PHO SPHAT BENZYL ALCOHOL BENZALKO NIUM CH	<b>E, DIBASIC</b> (UNI <b>E, MO NO BASIC</b> (UNII: LKG8494V	I: GR686LBA74) (UNII: 3980JIH2SW) VBH)				Strength
SODIUM PHO SPHAT SODIUM PHO SPHAT BENZYL ALCOHOL	<b>E, DIBASIC</b> (UNI <b>E, MONOBASIC</b> (UNII: LKG8494V ILORIDE (UNII: F	I: GR686LBA74) (UNII: 3980JIH2SW) VBH)	Marketi	ng Start Date	Mark	Strength

1 44 mL in 1 BOTTLE; Type 0: Not a Combination Product								
Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph final	part349	0 1/10/20 18						

Labeler - Healthlife of USA (079656178)

# Establishment

Name	Address	ID/FEI	Business Operations
Kingston Pharma LLC		080386521	manufacture(69517-609)

Revised: 1/2018

Healthlife of USA