

**RESTORAL- salicylic acid cream cream**  
**Peer Pharma Ltd.**

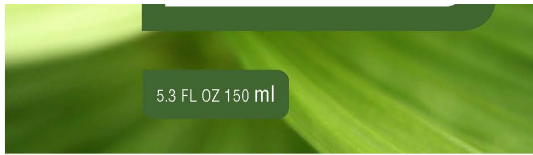
*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Restoral**



**RESTORAL**  
**PSORIASIS • 2% SALICYLIC ACID • CREAM**

<b>Drug Facts</b>	
<b>Active ingredients</b> Salicylic Acid, 2% .....	<b>Purpose</b> Psoriasis and seborrheic Dermatitis treatment.
<b>Uses</b> Relieves and helps prevent recurrence of skin itching • irritation • redness • flaking • scaling due to psoriasis and seborrheic dermatitis	
<b>Warnings</b> <b>For external use only</b> <b>Ask a doctor before use</b> if you have psoriasis that covers a large area of the body	
<b>When using this product</b> avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water	
<b>Stop use and ask a doctor if</b> condition worsens or does not improve after regular use as directed	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • apply to affected areas one to four times daily or as directed by a doctor • massage a liberal amount of the product into skin until thoroughly absorbed	
<b>Other information</b> Keep carton for full Drug Facts	
<b>Inactive ingredients</b> water, glyceryl stearate, PEG-100 stearate, glycerin, niacinamide, calendula officinalis flower oil, cannabis sativa seed oil, cetyl alcohol, butyrospermum parfi fishes butter, retinyl palmitate, alpha-tocopherol	



alcohol, butyrospermum parkii (shea butter), petrolatum, allantoin, steareth-21, tocopheryl acetate (vitamin E), lavandula angustifolia (lavender) oil, xanthan gum, dipotassium glycyrrhizate, aloe barbadensis leaf juice, triethanolamine, bisabolol, disodium EDTA, maris sal (dead sea mineral water).

Distributed by levona  
 99 Putnam Boulevard Atlantic Beach, New York 11509  
 Tel: +1 516 239 5111      Manufactured in Israel  
[www.levona-cosmetics.com](http://www.levona-cosmetics.com)      [Info@levona-cosmetics.com](mailto:Info@levona-cosmetics.com)

**Salicylic Acid, 2%**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Uses**

Relieves and helps prevent recurrence of skin itching

- irritation
- redness
- flaking
- scaling

due to psoriasis and seborrheic dermatitis

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<b>RESTORAL</b>			
salicylic acid cream cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69435-1805
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)		SALICYLIC ACID	3 g in 150 mL

## Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
STEARETH-21 (UNII: 53J3F32P58)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
WATER (UNII: 059QF0KO0R)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
SHEA BUTTER (UNII: K49155WL9Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
LEVOMENOL (UNII: 24WE03BX2T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERIN (UNII: PDC6A3C0OX)	
NIACINAMIDE (UNII: 25X51I8RD4)	
ALLANTOIN (UNII: 344S277G0Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1805-1	150 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/14/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/14/2018	

**Labeler** - Peer Pharma Ltd. (514678390)

**Registrant** - Peer Pharma Ltd. (514678390)

## Establishment

Name	Address	ID/FEI	Business Operations
Peer Pharma Ltd.		514678390	manufacture(69435-1805)