

**NIXODERM UNGUENTO- salicylic acid ointment**  
**Laboratorios Incobra S.A.**

*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.*

-----

**Active Ingredients :**

Salicylic Acid 2%

Acne Treatment

☐**Keep out of reach of children.**☐ If swallowed, contact physician or poison control center immediately.

For Skin Acne treatment

For relief, irritation, redness and of Acne

☐**Indications :**

\*For the treatment of Acne. Clears up acne pimples and blemishes, and allows skin to heal.  
Helps prevent new pimples and blemishes from forming.☐

☐**Directions**☐☐:

\*Clean the skin thoroughly before applying this product.

\*Cover the entire affected area with a thin layer one to three times daily, then gradually increase to two or three times daily if needed or as directed by a doctor

\*If bothersome dryness or peeling occurs, reduce application to once a day or every other day

☐**Warnings :**

\*For external use only.

\*Avoid contact with eyes. If contact occurs, rinse thoroughly with water

When using this product

\*Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use only topical acne medication at a time

\*Do not use without consulting a doctor if the condition appears over a large portion of the body.

Store at room temperature.

Other Ingredients: beeswax, BHT, benzoic acid, petrolatum, polysorbate 80, sulfur, zinc oxide.



<b>NIXODERM UNGUENTO</b>				
salicylic acid ointment				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70344-001	
<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	2 g in 100 g	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	YELLOW WAX (UNII: 2ZA36H0S2V)			
	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
	BENZOIC ACID (UNII: 8SKN0B0MIM)			
	PETROLATUM (UNII: 4T6H12BN9U)			
	POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
	SULFUR (UNII: 70FD1KFU70)			
	ZINC OXIDE (UNII: SOI2LOH54Z)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70344-001-01	20 g in 1 PACKAGE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/10/2016	

**Labeler** - Laboratorios Incobra S.A. (880003157)

## Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Incobra S.A.		880003157	manufacture(70344-001)

Revised: 2/2016

Laboratorios Incobra S.A.