

LABOFLEX ACNE SPOT CARE- salicylic acid 0.5% patch
Laboflex, Inc.

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.

LABOFLEX Acne Spot Care

Drug Facts

Active Ingredients

Salicylic Acid 0.5%

Purpose

Acne Treatment

Uses

- For the treatment of acne

Directions

- Cleanse thoroughly before applying this product
- Cover the entire affected area with patch
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two times daily if needed or as directed by a doctor
- If bothersome dryness or peeling occurs, reduce application to once a day or even every other day

Inactive Ingredients

Carboxymethylcellulose Sodium, Dihydroxyaluminum Aminoacetate, Edetate Sodium, Glycerin, Methyl- paraben, Mint Oil, Partially Neutralized Polyacrylic Acid, Polysorbate 80, Povidone-K90, Propylparaben, Propylene Glycol, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Purified Water

Questions of comments?

Call toll-free 1-800-655-0252 or email: wooshinlabo-us@wooshinmed.com

Warnings

For external use only.

Keep out of reach of children

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

Product Packaging

LaboFlex™

NDC 83655-105-21

Maximum Strength

LaboFlex™
ACNE SPOT CARE
Hydrogel Patch
Salicylic Acid 0.5%

LaboFlex™

Acne Spot Treatment

- Helps clear up acne, blemishes, pimples, blackheads, whiteheads
- Reduces swelling and redness
- Cleanses pores
- Smooths and softens skin
- Lasts up to 12 hours

30 Patches (0.78" / 2cm)

Drug Facts	
Active ingredient	Purpose
Salicylic Acid 0.5%	Acne Treatment
Uses For the treatment of acne	
Warnings :	
For external use only.	
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 one medication should be used. Do not use if you are allergic to the dressing or any of its components.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
■ Cleanse thoroughly before applying this product. ■ Cover the entire affected area with patch. ■ Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two times daily if needed or as directed by a doctor. ■ If bothersome dryness or peeling occurs, reduce application to once a day or even every other day.	
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Questions or comments? Call toll-free 1-800-655-0252 or email: wooshinbbe-us@wooshinmed.com	

LABO FLEX
PATENT PENDING
Manufactured for
139-19-0100
46 Corporate Park, Suite 130
Winn, LA 70095
Made in Slovenia

1 95685 00000 8



Maximum Strength

NDC 83655-105-11



*LaboFlex*TM
ACNE SPOT CARE

Hydrogel Patch

Salicylic Acid 0.5%

Acne Spot Treatment

- Helps clear up acne, blemishes, pimples, blackheads, whiteheads
- Reduces swelling and redness
- Cleanses pores
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30 Patches
(0.78" / 2cm)



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**LABO
FLEX**
PATCH GROUP

Manufactured for
Laboflex INC.
46 Corporate Park, Suite 140
Irvine CA 92606

Made in Slovenia

LOT



LABOFLEX ACNE SPOT CARE

salicylic acid 0.5% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83655-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MINT (UNII: FV98Z8GITP)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
WATER (UNII: 059QF0KO0R)	
TARTARIC ACID (UNII: W4888I119H)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83655-105-21	40 in 1 CARTON	09/27/2023	
1		0.25 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:83655-105-11	30 in 1 POUCH	09/27/2023	
2		0.25 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	M006	09/27/2023	
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Labeler - Laboflex, Inc. (128394050)

Registrant - Laboflex, Inc. (128394050)

Establishment

Name	Address	ID/FEI	Business Operations
WOOSHIN LAPACHE d.o.o.		507385209	manufacture(83655-105)

Revised: 9/2023

Laboflex, Inc.