

ACNE TREATMENT PADS- salicylic acid patch
Huijing (Shanghai) Bio-tech Co., 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.

Active ingredient

Salicylic acid 2%

Purpose

Acne treatment

Uses for the treatment of acne

Warnings

For external use only.

Avoid contact with eyes & lip, if contact occurs, flush thoroughly with water.

Ask a doctor or pharmacist before using other topical acne medications at the same time or immediately following use of this product. May increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

When using this product apply to affected area only. Do not use on broken skin or apply to large areas of the body.

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

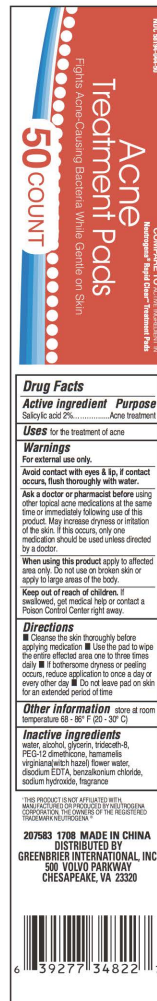
Directions

- Cleanse the skin thoroughly before applying medication
 - Use the pad to wipe the entire affected area one to three times daily
 - If bothersome dryness or peeling occurs, reduce application to once a day or every other day
- Do not leave pad on skin for an extended period of time.

Other information store at room temperature 68 - 86 F (20 - 30 C)

Inactive ingredients water, alcohol, glycerin, trideceth - 8, PEG-12 dimethicone, hamamelis virginiana (witch hazel) flower water, disodium EDTA,

benzalkonium chloride, sodium hydroxide,
fragrance



ACNE TREATMENT PADS

salicylic acid patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71537-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

ALCOHOL (UNII: 3K9958V90M)
GLYCERIN (UNII: PDC6A3C0OX)
TRIDECETH-8 (UNII: FZH06801NX)
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)
HAMAMELIS VIRGINIANA FLOWER WATER (UNII: 222MYC9QUV)
EDETATE DISODIUM (UNII: 7FLD91C86K)
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)
SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71537-001-02	50 in 1 CONTAINER	06/23/2017	
1	NDC:71537-001-01	2 mL in 1 PATCH; 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	06/23/2017	

Labeler - Huijing (Shanghai) Bio-tech Co., Ltd (544482337)

Establishment

Name	Address	ID/FEI	Business Operations
Huijing (Shanghai) Bio-tech Co., Ltd		544482337	manufacture(71537-001)

Revised: 6/2017

Huijing (Shanghai) Bio-tech Co., Ltd