

CLEANSING WIPES- salicylic acid swab

Nextcell Medical

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

Use

For the treatment of acne

Warnings

- For external use only
- Do not use if you have a known allergy to salicylic acid or aspirin
- Ask a doctor or pharmacist before use if you are using other topical acne medications at the same time or immediately following the use of this product. This may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.
- Stop use and ask a doctor if skin irritation occurs.
- Avoid contact with eyes. If contact occurs rinse eyes thoroughly with water.
- Avoid any unnecessary sun exposure and use a sunscreen.

Keep out of reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- peel label to open
- remove towlette and gently wipe over faace
- can be used to remove dirt, oil, and makeup
- avoid contact with eyes lips and mouth
- do not rinse
- discard towlette after use
- reseal pack to prevent from drying

Inactive ingredients

Alcohol, Aloe Barbadensis Leaf Extract, Aloe Barbadensis Leaf Juice, Alpha-Glucan Oligosaccharide, Amylopectin, Bioflavonoids, Brassica Oleracea, Italica (Broccoli) Extract, Capryloyl Glycine, Caprylyl Glycol, Cinnamomum Zeylanicum Barck Extract, Cocoamidopropyl PG-Dimonium, Chloride Phosphate, Decyl Glucoside, Dextrin, Ethylhexylglycerin, Hamamelis Virginiana (Witch Hazel) Water, Hexylene Glycol, Niacinamide, Phenoxyethanol, Polydextrose, Propanediol, Sarcosine, Water

This product has been scientifically formulated with a combination of clinically studied ingredients to quickly and gently cleanse and refresh the skin. In keeping with our commitment to safety and environmental responsibility, this formula is fragrance free, paraben free, and avoids many potentially harmful ingredients found in other products. This product is hypoallergenic and has been clinically and dermatologist tested.



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MEDICAL

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Made in the USA
of domestic and imported components

25 pre-moistened wipes
6.0 in x 7.75 in (15.24 cm x 19.69 cm)

Drug Facts (continued)

Directions • peel label to open • remove towelette and gently wipe over face • can be used to remove dirt, oil, and makeup • avoid contact with eyes, lips, and mouth • do not rinse • discard towelette after use • reseal pack to prevent from drying

Inactive ingredients

Water (Aqua), Hamamelis Virginiana (Witch Hazel) Water, Propanediol, Aloe Barbadensis Leaf Extract, Aloe Barbadensis Leaf Juice, Brassica Oleracea Italica (Broccoli) Extract, Cinnamomum (Zeylanicum) Bark Extract, Bioflavonoids, Alpha-Glucan Oligosaccharide, Decyl Glucoside, Dextrin, Polydextrose, Amylopectin, Niacinamide, Cocamidopropyl PG-Dimonium Chloride Phosphate, Sarcosine, Capryloyl Glycine, Alcohol Denat., Hexylene Glycol, Ethylhexylglycerin, Caprylyl Glycol, Phenoxyethanol

Other information

Store at 60° - 95° (15° - 35° C)

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ON-THE-GO CLEANSING WIPES FOR OILY OR ACNE PRONE SKIN

Cleansing wipes for oily or acne-prone skin are the perfect on-the-go solution to quickly clarify and refresh the skin. These soft, pre-moistened, textured wipes trap and remove excess oil, dirt, and other impurities from the skin. This formula contains 2% salicylic acid to help keep the skin clear and free of blemishes. The powerful combination of antioxidants helps to detoxify and protect the skin against environmental pollutants and stress factors.

Drug Facts

| Active ingredient | Purpose |
|-------------------|----------------|
| Salicylic Acid 2% | Acne Treatment |

Use for the treatment of acne

Warnings: For external use only

Do not use if you have a known allergy to Salicylic Acid or aspirin.

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

Stop use and ask a doctor if skin irritation occurs. • avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. • avoid unnecessary sun exposure and use a sunscreen.

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

CLEANSING WIPES

salicylic acid swab

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71613-001 |
| 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) | |
| witch hazel (UNII: 101I4J0U34) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| BRASSICA OLERACEA VAR. ITALICA WHOLE (UNII: DW4954EP53) | |
| CITRUS BIOFLAVONOIDS (UNII: BD70459I50) | |
| .ALPHA.-GLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| ICODEXTRIN (UNII: 2NX48Z0A9G) | |
| Polydextrose (UNII: VH2XOU12IE) | |
| AMYLOPECTIN (UNII: 4XO4QFV777) | |
| Niacinamide (UNII: 25X51I8RD4) | |
| COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4) | |
| SARCOSINE (UNII: Z711V88R5F) | |
| CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| CINNAMON BARK OIL (UNII: XE54U569EC) | |

Product Characteristics

| | | | |
|----------|-----------|--------------|--|
| Color | white | Score | |
| Shape | RECTANGLE | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71613-001-01 | 25 in 1 POUCH | 07/28/2017 | |
| 1 | | 3 mL in 1 APPLICATOR; 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 | 07/28/2017 | |

Labeler - Nextcell Medical (060650171)**Registrant** - Nextcell Medical (060650171)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Diamond Wipes International, Inc. | | 161104729 | manufacture(71613-001) |

Revised: 7/2017

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