

ENFUSELLE ACNE CLARIFYING- salicylic acid lotion

Shaklee Corporation

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.

enfuselle ACNE CLARIFYING COMPLEX □

Drug Facts

Active Ingredient

Salicylic Acid (0.5%)

Purpose

Acne treatment

Uses

For the treatment of acne.

Warnings

- **For external use only.**

When using this product

- Skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, use only one topical acne medication at a time.
- Keep out of eyes. Rinse with water to remove.

Keep out of reach of children.

In swallowed, get medical help or contact a Poison Control Center right away.

Directions for Use

- Clean the skin thoroughly before applying this product.
- Cover the entire affected area with a thin layer one to three times daily.
- Because excessive drying of the skin may occur, start with one application 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.

INACTIVE INGREDIENTS

Water/Eau, SD Alcohol 40-B, Cyclodextrin, Polysorbate 20, Xanthan Gum, 4-Terpineol*, Triethanolamine, Galactoarabinan, Zinc Gluconate, Sodium Coco PG-Dimonium Chloride Phosphate, Leptospermum Scoparium Branch/Leaf Oil, Tocopheryl Acetate, Dipotassium Glycyrrhizate, Panthenol, Disodium EDTA, Cetearyl Ethylhexanoate, Butylene Glycol, Nasturtium Officinale Extract, Arctium Lappa Root Extract, Aloe Barbadensis Leaf Juice, Pyridoxine HCL, Retinyl

Palmitate.

Principal Labeling

PARABEN FREE

salicylic acid
acne treatment

1fl. oz. 29mL
120 applications

All Skin Types

This exclusive treatment formula gently and comprehensively controls the factors that contribute to the cycle of acne-troubled skin.

Features an exclusive blend of nourishing antioxidants and purifying botanicals to help normalize sebum, unclog pores, speed healing, and reduce redness caused by acne. With continued use, skin will become visibly smoother, clearer, and shine free.

- Not tested on animals
- 100% free of occlusive oils

Shaklee

Dist. by/par

Shaklee Corporation

4747 Willow Road

Pleasanton, CA 94588 USA

Item #39075

- Breakthrough patented formula
- Contains botanical extracts:
 - tea tree (*Melaleuca alternifolia*) oil
 - manuka (*Leptospermum scoparium*) oil
 - licorice (*Dipotassium glycyrrhizate*) extract
 - burdock (*Arctium lappa*) root extract
 - watercress (*Nasturtium officinale*) extract
 - aloe vera (*Aloe barbadensis*) leaf juice
- Features antioxidant vitamins A and E
- Gentle enough to use daily for maximum acne control
- 100% fragrance and paraben free

- Allergy tested
- Clinically formulated
- Dermatologist tested

Do not store at
temperatures above 100°F.
U.S. Patent: 6,403,110

Apply this exclusive facial formula to help keep skin blemish free, speed healing and reduce redness caused by acne. Gentle enough to use daily, this unique blend of botanicals and nourishing antioxidants effectively controls the factors that contribute to the cycle of acnetroubled skin.

WARNINGS: For external use only. Keep out of eyes. “Keep out of reach of children. If excessive dryness or peeling occurs, reduce the application to once a day or every other day.

Directions: Apply one to three times daily after cleansing and toning. Allow to dry after application. Follow with the Enfuselle treatment or moisturizer for your skin type.

Package Labeling:

e n f u s e l l e[®]

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e n f u s e l l e[®]
 by Shaklee

ACNE CLARIFYING
 COMPLEX™

COMPLEXE CLARIFIANT

POUR L'ACNÉ

PARABEN FREE
 SANS PARABEN

salicylic acid
 acne treatment

1 fl. oz. 29 mL
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 *Active ingredient of Tea Tree Oil

e n f u s e l l e[®]

EXP: LOT:

ENFUSELLE ACNE CLARIFYING

salicylic acid lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59899-002
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 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
4-TERPINEOL, (+/-)- (UNII: L65MV77ZG6)	
TROLAMINE (UNII: 9O3K93S3TK)	
GALACTOARABINAN (UNII: SL4SX1O487)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
MANUKA OIL (UNII: M6QU9ZUH2X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
PANTHENOL (UNII: WV9CM0O67Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
ARCTIUM LAPPA ROOT (UNII: 597E9B13Z3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59899-002-01	1 in 1 CARTON	08/08/2013	
1		29 mL in 1 TUBE; 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	08/08/2013	

