

ACNEWORX- salicylic acid gel
DermWorx Incorporated

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.

AcneWorx® Gentle Moisturizing Clear Acne Treatment Gel
(2% Salicylic Acid)

Active ingredient

Salicylic Acid 2%

Purpose

Treatment of acne

Uses

For the treatment of acne

Warnings

For external use only. Avoid contact with eyes and mucous membranes. If contact occurs, wash thoroughly with water.

Ask a doctor or pharmacist

before use if you are using other topical medications at the same time.

Stop use

if excessive irritation of the skin develops.

Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center immediately.

Directions

Cleanse the skin thoroughly before applying medication. Cover the affected area with a thin layer 1-3 times daily.

Inactive ingredients

Water, Diisopropyl Adipate, Cyclomethicone, Glyceryl Stearate, Glyceryl Dilaurate, Glycerin, Ethoxydiglycol, Ethylhexyl Palmitate, L-Arginine, Stearoxymethicone/Dimethicone Copolymer, Cetearyl Alcohol, Cetyl Alcohol, PEG-150 Stearate, Polysorbate 80, Ethylene/Acrylic Acid Copolymer, Glycine Soja (soybean) Sterol, Tocopheryl Acetate, Phenoxyethanol, Cetearyl Glucoside, Xanthan Gum, Methylparaben, Disodium EDTA, Superoxide Dismutase, Citric Acid.

Patient Information

AcneWorx® is a maximum strength acne treatment that clears acne blemishes fast and helps prevent new breakouts before they become visible without the irritation caused by similar solvent-based formulations. AcneWorx® is a nano-based formulation utilizing Novasome® technology, a proprietary microsphere technology containing an effective acne-fighting medicine that penetrates pores to eliminate most acne blemishes.

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Indications

For the treatment of acne, especially, adult acne in men and women.

What is the Cause of Adult Acne?

Acne affects almost everyone, with more than 90% of all adolescents experiencing some form of acne and nearly 50% of all adult women and 25% of all adult men facing this skin disorder. Acne is prevalent in both men and women and is present in all ethnic backgrounds making it one of the most widespread medical conditions in the world.

A common misnomer is that acne is only for teenagers and will simply disappear once puberty is over. In fact, recent statistics reported by the American Dermatology Association suggest that the median age for patients being treated for acne has actually increased from approximately 20.5 to 26.5 years of age. More than 17 million adults in the U.S. are diagnosed with acne with over 50% of adult women and 25% of adult men having this skin disease.

So if you're one of many men or a woman with adult acne, you may be asking yourself what are the causes of acne.

Etiology (Causes) of Adult Acne

The underlying factors responsible for teenage acne are the same as those for adult acne:

1. Hormones

For the majority of acne sufferers puberty marks the onset of trouble, this is the time when the body begins to produce hormones called androgens. Testosterone in the skin can be metabolized to dihydrotestosterone, which causes the sebaceous glands to enlarge and increase sebum production. In acne sufferers, the sebaceous glands over-respond to androgens, sometimes well into adulthood. Androgens may also contribute to acne flare-ups associated with the menstrual cycle and, on occasion, pregnancy.

2. Over secretion of Sebaceous Glands

When the sebaceous gland is stimulated by dihydrotestosterone it produces extra sebum. Under normal circumstances sebum moves up the follicle toward the surface, the sebum mixes with normal skin bacteria and dead skin cells that have been shed from the lining of the follicle and removes them to the skin surface. While this process is normal, the presence of extra sebum in the follicle increases the

chances of clogging and resultant acne.

3. Clogged Pores

Normally, dead cells within the follicle shed gradually and are expelled onto the skin's surface. In individuals with over-active sebaceous glands, these cells are shed more rapidly and mix with the surplus of sebum. The dead skin cells form a plug in the follicle causing either a blackhead or whitehead.

4. Bacteria

The bacterium, *Propionibacterium acnes* (*P. acnes*), is normally present in all skin types and is part of the skin's natural sebum maintenance system. Once a follicle is plugged the excess sebum supplies a rich environment for the *P. acnes* bacteria to multiply rapidly. This microenvironment creates the chemical reaction known as inflammation in the follicle and surrounding skin.

5. Local Inflammation

When your body encounters unwanted bacteria, it sends white blood cells to attack the “intruders”. This process is called chemotaxis and results in the inflammatory response, which causes pimples to become red, swollen, and painful. The inflammatory response is different for everyone, but studies have shown that it is especially strong in adult women. Thus, causing many adult women to experience particularly painful acne pimples.

Treatment of Adult Acne

In adult acne it is especially important to limit the number of pimples since dermatologists have known for many years that adult acne is more likely to leave permanent physical scars. The increase prevalence of scarring or pox marks is due to the fact that as the skin ages and loses collagen. It is much harder for the skin to repair itself after tissue damage that is caused by inflammation and enlarged pores associated with acne.

The standard treatments for adult acne are similar to those employed for adolescent acne, mainly topical products. These products often dry not only “pimples” but also the skin around them.

Salicylic acid is a widely used and well established ingredient in the pharmaceutical and healthcare areas. It has been used extensively in dermatological formulations as an exfoliate, anti-acne, anti-wart, anti-psoriatic and anti-aging agent.

The Food and Drug Administration Advisory Panel reviewed a number of well-controlled clinical studies for the treatment of acne and adult acne. In a primary 12-week acne study of 180 subjects, good to excellent results for total lesions were obtained by 40 percent of the subjects using 2% salicylic acid.

Similarly, the placebo showed improvement in only 5% of the subjects while only 2% of the subjects using benzoyl peroxide showed improvement. Salicylic acid was particularly effective in treating inflammatory lesions (papules and pustules) where 80% of the subjects had good or excellent results compared to 11% for the vehicle and 15% for benzoyl peroxide. Salicylic acid has clearly shown its superiority over benzoyl peroxide in the treatment of acne.

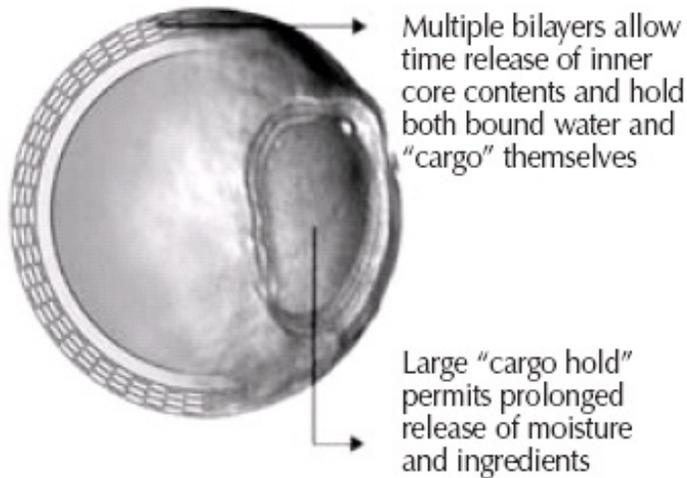
Despite its wide use, salicylic acid has some basic formulation limitations, which do not allow its optimal properties to be achieved. The very low aqueous solubility of salicylic acid is a major obstacle in attaining significantly improved formulations and, hence, efficacy within a short time frame. In order to overcome the solubility issues, current marketed products have used various solvents (i.e. acetone, alcohol, etc.) to increase the solubility. However, these organic solvents are also skin irritants to the surrounding healthy skin and act as drying agents on the skin. AcneWoRx® does not contain any organic solvents.

The therapeutic effectiveness of salicylic acid depends upon the presence of moisture. Therefore, salicylic acid is usually incorporated into vehicles that occlude the area and promote hydration causing maceration of the skin. AcneWoRx® incorporates a novel, patented, nanoparticle proprietary process in

its formulation. Formulations with nanoparticles containing salicylic acid provide greater penetration of lesions without an increased potential for irritation from the formulation.

The microvesicle process significantly increases this compound's aqueous solubility, penetrability and stability. Novasome® technology utilizes proprietary organized lipid structures, lipid vesicle encapsulation technologies, cellulose structures, and micellar nanoparticles. This technology provides for a nanoparticle in an aqueous transport system. Because the system is aqueous, irritating organic solvents such as ether, acetone, alcohol and witch hazel that are currently used in other products containing salicylic acid are eliminated without sacrificing efficacy relating to concentration.

The Patented Microvesicle



The microvesicle contains 3 moisture compartments: water outside of vesicle, water inside the core of the vesicle, and osmotically bound water in between the layers of the vesicle

Warnings

For external use only.

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 product may result in increased dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

When using this product avoid contact with eyes and mucous membranes. If contact occurs, flush thoroughly with water.

Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center immediately.

Cautions:

Discontinue use if excessive irritation of the skin develops.

Directions:

Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer 1-3 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.

How Supplied:

1.0 fl oz (30 mL) Tube

NDC 28109-010-01



Distributed by DermWorx, Inc.

Hollywood, FL 33022

Principal Display Panel - Tube Label

28109-010-01

AcneWorx®

Gentle Moisturizing

Clear Acne

Treatment Gel

(2% Salicylic Acid)

AcneWorx® incorporates

Novasome® Technology,

a breakthrough nano-particle

delivery system.

Reduces acne blemishes

within 8 hours

and helps prevent

new acne pimples

before they become visible

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DermWorx

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Hollywood, FL 33022

Tube Label

Principal Display Panel - Outer Carton Label

AcneWorx®
Gentle Moisturizing
Clear Acne
Treatment Gel
(2% Salicylic Acid)

Unit contains:

6 1.0 fl oz (30mL) TUBES

28109-010-06



Outer Carton Label

ACNEWORX

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:28 109 -0 10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.6 g in 30 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:28 109 -0 10 -06	6 in 1 CARTON		
1	NDC:28 109 -0 10 -01	1 in 1 CARTON		

1	30 mL in 1 TUBE		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333	01/14/2008	

Labeler - DermWorx Incorporated (015678067)

Establishment			
Name	Address	ID/FEI	Business Operations
IGI Laboratories, Inc.		011036910	MANUFACTURE

Revised: 2/2010

DermWorx Incorporated