

Manufactured for:
Innocutis Holdings, LLC
Charleston, SC 29401
Toll Free: 1-800-499-4468
www.innocutis.com
www.inovaAcne.com



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U.S. Patent Nos. 6,582,727; 6,340,477;
6,884,060

INSTRUCTIONS
for Inova® 4%
or Inova® 8%

EVENING - 30 Min. Before Bedtime

1 - Wash

Wash the treatment area with a mild non-irritating cleanser, rinse and pat dry. Your doctor may recommend a mild cleanser specifically for your skin type.

2 - Purple Pad OR Blue Pad

Apply the Purple Pad (benzoyl peroxide 4%) OR Blue Pad (benzoyl peroxide 8%) to your face in the evening. Evenly distribute the medication around the treatment area avoiding scrubbing or strong pressure while applying. Avoid hair, clothing and eyes as benzoyl peroxide may cause bleaching on contact.

MORNING - Before You Leave Home

1 - Wash

Wash the treatment area with a mild non-irritating cleanser, rinse and pat dry.

2 - Vitamin E Capsule

Apply the Vitamin E capsule to the entire treatment area. Twist off the small end to release the product. Use your fingertips to distribute evenly across the treatment area.

*If any stinging, burning, or irritation occurs, please rinse off and call your doctor.

INSTRUCTIONS
for Inova® ACT 4/1
or Inova® ACT 8/2

EVENING - 30 Min. Before Bedtime

1 - Wash

Wash the treatment area with a mild non-irritating cleanser, rinse and pat dry. Your doctor may recommend a mild cleanser specifically for your skin type.

2 - Purple Pad OR Blue Pad

Apply the Purple Pad (benzoyl peroxide 4%) OR Blue Pad (benzoyl peroxide 8%) to your face in the evening. Evenly distribute the medication around the treatment area avoiding scrubbing or strong pressure while applying. Avoid hair, clothing and eyes as benzoyl peroxide may cause bleaching on contact.

MORNING - Before You Leave Home

1 - Wash

Wash the treatment area with a mild non-irritating cleanser, rinse and pat dry.

2 - Yellow Pad

Apply the Yellow Pad (salicylic acid) to the face after cleansing. Evenly distribute the medication around the treatment area avoiding scrubbing or strong pressure while applying. Let dry 3-5 minutes.

3 - Vitamin E Capsule

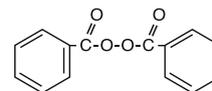
Apply the Vitamin E capsule to the entire treatment area. Twist off the small end to release the product. Use your fingertips to distribute evenly across the treatment area.

**PLEASE SEE INSTRUCTIONS
ON BACK PANEL
BEFORE APPLYING**

inova®
(benzoyl peroxide)
EASY PAD®

FOR EXTERNAL USE ONLY

DESCRIPTION: Inova® (benzoyl peroxide) 4% and 8% Easy Pad® are topical preparations containing benzoyl peroxide for use in the treatment of acne vulgaris. Benzoyl peroxide is an oxidizing agent that possesses antibacterial properties and is classified as a keratolytic. Benzoyl peroxide (C₁₄H₁₀O₂) is represented by the following chemical structure:



Inova® (benzoyl peroxide) 4% Easy Pad® contains benzoyl peroxide USP 4% as the active ingredient in a formulation consisting of: carbomer, disodium EDTA, disodium lauryl sulfosuccinate, glycerin, hydrated silica, methylparaben, poloxamer 182, purified water, sodium hydroxide.

Inova® (benzoyl peroxide) 8% Easy Pad® contains benzoyl peroxide USP 8% as the active ingredient in a formulation consisting of: carbomer, dicaprylyl carbonate, diisopropyl adipate, disodium EDTA, disodium lauryl sulfosuccinate, ethylene brassylate, glycerin, hydrated silica, methylparaben, phenethyl benzoate, poloxamer 182, purified water, sodium hydroxide.

CLINICAL PHARMACOLOGY: The mechanism of action of benzoyl peroxide is not totally understood but its antibacterial activity against *Propionibacterium* acnes is thought to be a major mode of action, in addition, patients treated with benzoyl peroxide show a reduction in lipids and free fatty acids, and mild desquamation (drying and peeling activity) with simultaneous reduction in comedones and acne lesions. Little is known about the percutaneous penetration, metabolism, and excretion of benzoyl peroxide, although it has been shown that benzoyl peroxide absorbed by the skin is metabolized to benzoic acid and then excreted as benzoate in the urine. There is no evidence of systemic toxicity caused by benzoyl peroxide in humans.

DIRECTION 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.

Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated elsewhere on this label.

Do not use if you:

- have very sensitive skin
- are sensitive to benzoyl peroxide

CONTRAINDICATIONS: These preparations are contraindicated in patients with a history of hypersensitivity to any of their components.

WARNINGS: For external use only.

When using this product:

- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the

product less frequently or in a lower concentration.

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

PRECAUTIONS:

Pregnancy: Teratogenic Effects:

Pregnancy Category C: Animal reproduction studies have not been conducted with benzoyl peroxide. It is not known whether benzoyl peroxide can cause fetal harm when administered to a pregnant woman or can effect reproduction capacity. Benzoyl peroxide should be used by a pregnant woman only if clearly needed. There are no available data on the effect of benzoyl peroxide on the later growth, development and functional maturation of the unborn child.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when benzoyl peroxide is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

Store at controlled room temperature:
15° - 30° C (59° - 86° F).

PRO:VITAMIN E5

FOR TOPICAL USE ONLY

DESCRIPTION: Pro:Vitamin E5 contains tocopherol 5% as the principal component. Other ingredients: cyclopentasiloxane, dimethicone crosspolymer and helianthus annuus seed oil.

Store at controlled room temperature:
15° - 30° C (59° - 86° F).

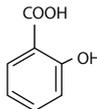


Salicylic Acid

EASY PAD®

FOR EXTERNAL USE ONLY

DESCRIPTION: Salicylic Acid 1% and 2% Easy Pad® are topical preparations containing salicylic acid for use in the treatment of acne vulgaris. Salicylic acid is a 2-hydroxybenzoic acid and is represented by the following chemical structure:



Salicylic Acid 1% Easy Pad® contains salicylic acid USP 1% as the active ingredient in a formulation consisting of: ammonium lauryl sulfate, ammonium xylenesulfonate, citric acid, DMDM hydantoin, herbal essence, menthol, purified water, retinyl palmitate, simethicone, sodium ascorbyl phosphate, sodium borate, tetrasodium EDTA, tocopheryl acetate, water (and) PPG-26 buteth-26 (and) PEG-40 hydrogenated castor oil.

Salicylic acid 2% Easy Pad® contains salicylic acid USP 2% as the active ingredient in a formulation consisting of: ammonium lauryl sulfate, ammonium xylenesulfonate, citric acid, DMDM hydantoin, herbal essence, menthol, PPG-5-CETETH-20, purified water, simethicone, sodium borate, tetrasodium EDTA.

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.

CONTRAINDICATIONS: These preparations are contraindicated in patients with a history of hypersensitivity to any of their components.

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 use one topical acne medication at a time.

Store at controlled room temperature:
15° - 30° C (59° - 86° F).

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HOW SUPPLIED:

Inova® (benzoyl peroxide) 4% Easy Pad® and tocopherol 5%: available in a box containing 30 - 3g individual foil pouch pads of benzoyl peroxide 4% and 28 capsules of topical tocopherol 5%.
NDC 68712-013-01

Inova® 4/1 Acne Control Therapy (benzoyl peroxide) 4%, (salicylic acid) 1% Easy Pad® and tocopherol 5%: available in a box containing 30 - 3g individual foil pouch pads of benzoyl peroxide 4%, 30 - 3g individual foil pouch pads of salicylic acid 1%, and 28 capsules of topical tocopherol 5%.
NDC 68712-014-01

Inova® (benzoyl peroxide) 8% Easy Pad® and tocopherol 5%: available in a box containing 30 - 3g individual foil pouch pads of benzoyl peroxide 8% and 28 capsules of topical tocopherol 5%.
NDC 68712-023-01

Inova® 8/2 Acne Control Therapy (benzoyl peroxide) 8%, (salicylic acid) 2% Easy Pad® and tocopherol 5%: available in a box containing 30 - 3g individual foil pouch pads of benzoyl peroxide 8%, 30 - 3g individual foil pouch pads of salicylic acid 2%, and 28 capsules of topical tocopherol 5%.
NDC 68712-021-01