

VANOXIDE HC- benzoyl peroxide, hydrocortisone lotion

Summers Laboratories Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SUMMERS LABS (as PLD) - VANOXIDE (11086-032)

ACTIVE INGREDIENTS:

BENZOYL PEROXIDE 5%

HYDROCORTISONE 0.5%

Apply with caution on neck and/or other sensitive areas. There may be a slight transitory stinging or burning sensation on initial applications. Colored or dyed garments and linens may be bleached by the action of benzoyl peroxide. If irritation or sensitivity is observed, discontinue use and consult your physician.

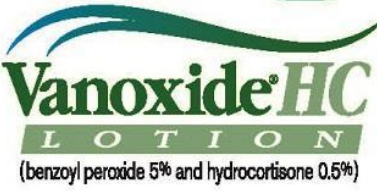

KEEP OUT OF REACH OF CHILDREN.

TO THE PHARMACIST:

Prior to dispensing, add powder content of vial* to lotion. Shake bottle thoroughly to disperse completely. After addition of powder, place expiration date of 3 months on the bottle.

*Benzoyl-Pak™

- Keep away from eyes. FOR TOPICAL USE ONLY. Not for ophthalmic, oral or intravaginal use.
- Shake well before using.
- Keep tightly closed.
- Store at room temperature. 20°-25° C (68°-77° F). Do not freeze.

<p>TO THE PHARMACIST: Prior to dispensing, please add powder content of vial to lotion. Shake bottle thoroughly to disperse completely. Place expiration date of 3 months on the bottle.</p> <p>Indications: An aid in the treatment of acne and oily skin.</p> <p>Directions: Cleanse affected areas. Apply thin film, 1 to 3 times daily, or as directed by your physician.</p> <p>Caution: Federal law prohibits dispensing without a prescription.</p>	<p>NDC 11086-032-01</p>  <p>Vanoxide[®]HC LOTION (benzoyl peroxide 5% and hydrocortisone 0.5%)</p> <p>NET WT 25g (0.88 oz.) as dispensed</p> 	<p>Vanoxide[®]-HC Lotion (Vanishes on Application) Apply with caution on neck and/or other sensitive areas. There may be a slight transitory stinging or burning sensation on initial applications. Colored or dyed garments and linens may be bleached by the action of benzoyl peroxide.</p> <p>If irritation or sensitivity is observed, discontinue use and consult your physician.</p> <p>Rx Only</p>	<p>TO THE PHARMACIST: Prior to dispensing, add powder content of vial* to lotion. Shake bottle thoroughly to disperse completely. After addition of powder, place expiration date of 3 months on the bottle. *Benzoyl-Pak™</p> <ul style="list-style-type: none">• Keep away from eyes. FOR TOPICAL USE ONLY. Not for ophthalmic, oral or intravaginal use.• Shake well before using.• Keep out of the reach of children.• Keep tightly closed.• Store at room temperature. 20°-25° C (68°-77° F). Do not freeze. <p>Marketed by: Summers Laboratories, Inc. Collegeville, PA 19426 1-800-533-SKIN (7546) • www.sumlab.com</p> <p>↑ FOR COMPLETE PRODUCT INFORMATION ↓ ↑ TEAR THIS FLAP AND OPEN CARTON ↓</p>
--	--	---	---

NDC 11086-032-01



Vanoxide^{HC}
LOTION
(benzoyl peroxide 5% and hydrocortisone 0.5%)

NET WT 25 g (as dispensed)

Description: After adding contents of vial to lotion base, the mixture contains hydrocortisone 0.5% w/w, and benzoyl peroxide 5% w/w.

Directions: Cleanse affected areas. Apply 1 to 3 times daily with gentle massaging until it disappears into skin, or as directed by physician.

Indications: For complete product information, see package insert.

Warnings: Keep away from eyes. For external use only. Keep out of reach of children. Store at room temperature. Keep tightly closed. May bleach garments and linens.

Caution: Federal law prohibits dispensing without prescription. USE WITHIN 3 MONTHS AFTER MIXING.

SHAKE WELL BEFORE USING.

Marketed by:
Summers Laboratories, Inc.
Collingville, PA 19426
1-800-533-SKIN (7546)
www.summlab.com

VANOXIDE HC

benzoyl peroxide, hydrocortisone lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:11086-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 g
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.5 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11086-032-01	25 g in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/01/2009	

Labeler - Summers Laboratories Inc (002382612)

Revised: 10/2023

Summers Laboratories Inc