FINACEA™

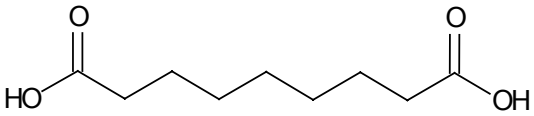
(azelaic acid) Gel, 15%

For Dermatologic Use Only – Not for Ophthalmic, Oral, or Intravaginal Use

Rx only

DESCRIPTION

FINACEA™ (azelaic acid) Gel, 15%, contains azelaic acid, a naturally occurring saturated dicarboxylic acid. Chemically, azelaic acid is 1,7-heptanedicarboxylic acid, with the molecular formula $C_9 H_{16} O_4$, a molecular weight of 188.22, and the structural formula:



[HOOC-$(CH_2)_7$-COOH]

Azelaic acid is a white, odorless crystalline solid that is poorly soluble in water at 20°C (0.24%), but freely soluble in boiling water and in ethanol.

Each gram of FINACEA™ Gel, 15%, contains 0.15 gm azelaic acid (15% w/w) as the active ingredient in an aqueous gel base containing benzoic acid (as a preservative), disodium-EDTA, lecithin, medium-chain triglycerides, polyacrylic acid, polysorbate 80, propylene glycol, purified water, and sodium hydroxide to adjust pH.

CLINICAL PHARMACOLOGY

The mechanism(s) by which azelaic acid interferes with the pathogenic events in rosacea are unknown.

Pharmacokinetics: The percutaneous absorption of azelaic acid after topical application of FINACEA™ Gel, 15%, could not be reliably determined. Mean plasma azelaic acid concentrations in rosacea patients treated with FINACEA™ Gel, 15%, twice daily for at least 8 weeks are in the range of 42 to 63.1 ng/mL. These values are within the maximum concentration range of 24.0 to 90.5 ng/mL observed in rosacea patients treated with vehicle only.

This indicates that FINACEA™ Gel, 15%, does not increase plasma azelaic acid concentration beyond the range derived from nutrition and endogenous metabolism.

In vitro and human data suggest negligible cutaneous metabolism of ^{3}H-azelaic acid 20% cream after topical application. Azelaic acid is mainly excreted unchanged in the urine, but undergoes some ß-oxidation to shorter chain dicarboxylic acids.

CLINICAL STUDIES

FINACEA™ Gel, 15%, was evaluated for the treatment of mild to moderate papulopustular rosacea in 2 clinical trials comprising a total of 664 (333 active to 331 vehicle). Both trials were multicenter, randomized, double-blind, vehicle-controlled 12-week studies with identical protocols. Overall, 92.5% of patients were Caucasian and 73% of patients were women, and the mean age was 49 (range 21 to 86) years. Enrolled patients had mild to moderate rosacea with a mean lesion count of 18 (range 8 to 60) inflammatory papules and pustules. Subjects without papules and pustules, with nodules, rhinophyma, or ocular involvement, and a history of hypersensitivity to propylene glycol or to any other ingredients of the study drug were excluded. FINACEA™ Gel, 15%, or its vehicle were to be applied twice daily for 12 weeks; no other topical or systemic medication affecting the course of rosacea and/or evaluability was to be used during the studies. Patients were instructed to avoid spicy foods, thermally hot foods and drinks, and alcoholic beverages during the study, and to use only very mild soaps or soapless cleansing lotion for facial cleansing.

The primary efficacy endpoints were both 1) change from baseline in inflammatory lesion counts and 2) success defined as a score of clear or minimal with at least a 2 step reduction from baseline on the Investigator's Global Assessment (IGA):

CLEAR:

No papules and/or pustules; no or residual erythema; no or mild to moderate telangiectasia

MINIMAL:

Rare papules and/or pustules; residual to mild erythema; mild to moderate telangiectasia

MILD:

Few papules and/or pustules; mild erythema; mild to moderate telangiectasia

MILD TO MODERATE:

Distinct number of papules and/or pustules; mild to moderate erythema; mild to moderate telangiectasia

MODERATE:

Pronounced number of papules and/or pustules; moderate erythema; mild to moderate telangiectasia

MODERATE TO SEVERE:

Many papules and/or pustules, occasionally with large inflamed lesions; moderate erythema; moderate degree of telangiectasia

SEVERE:

Numerous papules and/or pustules, occasionally with confluent areas of inflamed lesions; moderate or severe erythema; moderate or severe telangiectasia

Primary efficacy assessment was based on the intent-to-treat (ITT) population with last observation carried forward (LOCF).

Both studies demonstrated a statistically significant difference in favor of FINACEA™ Gel, 15%, over its vehicle in reducing the number of inflammatory papules and pustules associated with rosacea and with success on the IGA in the ITT-LOCF population at the end of treatment.

Table 2. Inflammatory Papules and Pustules (ITT population)

	Study One FINACEA™ Gel, 15% N = 164	Study One VEHICLE N = 165	Study Two FINACEA™ Gel, 15% N = 167	Study Two VEHICLE N = 166
Mean lesion count				
Baseline	17.5	17.6	17.9	18.5
End of Treatment [1]	6.8	10.5	9.0	12.1
Mean Percent Reduction				
End of Treatment [1]	57.9%	39.9%	50.0%	38.2%

[1] ITT population with last observation carried forward (LOCF);

FINACEA™ Gel, 15%, was superior to the vehicle with regard to success based on the investigator's global assessment of rosacea on a 7-point static score at the end of treatment, (ITT population; Table 3).

Table 3. Investigator's Global Assessment at the End of Treatment[1]

	Study One FINACEA™ Gel, 15% N = 164	Study One VEHICLE N = 165	Study Two FINACEA™ Gel, 15% N = 169	Study Two VEHICLE N = 166
CLEAR, MINIMAL or MILD at End of Treatment (% of Patients)	61%	40%	62%	48%

[1] ITT population with last observation carried forward (LOCF);

INDICATIONS AND USAGE

FINACEA™ Gel, 15%, is indicated for topical treatment of inflammatory papules and pustules of mild to moderate rosacea. Patients should be instructed to avoid spicy foods, thermally hot foods and drinks, alcoholic beverages and to use only very mild soaps or soapless cleansing lotion for facial cleansing.

CONTRAINDICATIONS

FINACEA™ Gel, 15%, is contraindicated in individuals with a history of hypersensitivity to propylene glycol or any other component of the formulation.

WARNINGS

FINACEA™ Gel, 15%, is for dermatologic use only, and not for ophthalmic, oral or intravaginal use.

There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with dark complexion, these patients should be monitored for early signs of hypopigmentation.

PRECAUTIONS

General: Contact with the eyes should be avoided. If sensitivity or severe irritation develops with the use of FINACEA™ Gel, 15%, treatment should be discontinued and appropriate therapy instituted. The safety and efficacy of FINACEA™ Gel, 15%, has not been studied beyond 12 weeks.

Information for Patients: Patients using FINACEA™ Gel, 15%, should receive the following information and instructions:

- FINACEA™ Gel, 15%, is to be used only as directed by the physician.
- FINACEA™ Gel, 15%, is for external use only. It is not to be used orally, intravaginally, or for the eyes.

  Cleanse affected area(s) with a very mild soap or a soapless cleansing lotion and pat dry with a soft towel before applying FINACEA™ Gel, 15%. Avoid alcoholic cleansers, tinctures and astringents, abrasives and peeling agents.

- Avoid contact of FINACEA™ Gel, 15%, with the mouth, eyes and other mucous membranes. If it does come in contact with the eyes, wash the eyes with large amounts of water and consult a physician if eye irritation persists.

- The hands should be washed following application of FINACEA™ Gel, 15%.

- Cosmetics may be applied after FINACEA™ Gel, 15%, has dried.

- Skin irritation (e.g., pruritus, burning, or stinging) may occur during use of FINACEA™ Gel, 15%, usually during the first few weeks of treatment. If irritation is excessive or persists, use of FINACEA™ Gel, 15%, should be discontinued, and patients should consult their physician (see **ADVERSE REACTIONS**).

- Avoid any foods and beverages that might provoke erythema, flushing, and blushing (including spicy food, alcoholic beverages, and thermally hot drinks, including hot coffee and tea).

- Patients should report abnormal changes in skin color to their physician.

- Avoid the use of occlusive dressings or wrappings.

Drug Interactions*:* There have been no formal studies of the interaction of FINACEA™ Gel, 15%, with other drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility*:* Long-term animal studies have not been performed to evaluate the carcinogenic potential of FINACEA™ Gel, 15%. Azelaic acid was not mutagenic or clastogenic in a battery of in vitro (Ames assay, HGPRT in V79 cells {Chinese hamster lung cells}, and chromosomal aberration assay in human lymphocytes) and in vivo (dominant lethal assay in mice and mouse micronucleus assay) genotoxicity tests.

Oral administration of azelaic acid at dose levels up to 2500 mg/kg/day (162 times the maximum recommended human dose based on body surface area) did not affect fertility or reproductive performance in male or female rats.

Pregnancy: *Teratogenic Effects*: *Pregnancy Category B*

There are no adequate and well-controlled studies of topically administered azelaic acid in pregnant women. The experience with FINACEA™ Gel, 15%, when used by pregnant women is too limited to permit assessment of the safety of its use during pregnancy.

Dermal embryofetal developmental toxicology studies have not been performed with azelaic acid, 15%, gel. Oral embryofetal developmental studies were conducted with azelaic acid in rats, rabbits, and cynomolgus monkeys. Azelaic acid was administered during the period of organogeneisis in all three animal species. Embryotoxicity was observed in rats, rabbits, and monkeys at oral doses of azelaic acid that generated some maternal toxicity. Embryotoxicity was observed in rats given 2500 mg/kg/day (162 times the maximum recommended human dose based on body surface area), rabbits given 150 or 500 mg/kg/day (19 or 65 times the maximum recommended human dose based on body surface area) and cynomolgus monkeys given 500 mg/kg/day (65 times the maximum recommended human dose based on body surface area) azelaic acid. No teratogenic effects were observed in the oral embryofetal developmental studies conducted in rats, rabbits and cynomolgus monkeys.

An oral peri- and post-natal developmental study was conducted in rats. Azelaic acid was administered from gestational day 15 through day 21 postpartum up to a dose level of 2500 mg/kg/day. Embryotoxicity was observed in rats at an oral dose that generated some maternal toxicity (2500 mg/kg/day; 162 times the maximum recommended human dose based on body surface area). In addition, slight disturbances in the post-natal development of fetuses was noted in rats at oral doses that generated some maternal toxicity (500 and 2500 mg/kg/day; 32 and 162 times the maximum recommended human dose based on body surface area). No effects on sexual maturation of the fetuses were noted in this study.

Because animal reproduction studies are not always predictive of human response, this drug should be used only if clearly needed during pregnancy.

Nursing Mothers: Equilibrium dialysis was used to assess human milk partitioning in vitro. At an azelaic acid concentration of 25 µg/mL, the milk/plasma distribution coefficient was 0.7 and the milk/buffer distribution was 1.0, indicating that passage of drug into maternal milk may occur. Since less than 4% of a topically applied dose of AZELEX® Cream, 20%, is systemically absorbed, the uptake of azelaic acid into maternal milk is not expected to

cause a significant change from baseline azelaic acid levels in the milk. However, caution should be exercised when FINACEA™ Gel, 15%, is administered to a nursing mother.

***Pediatric Use**: Safety* and effectiveness of FINACEA™ Gel, 15%, in pediatric patients have not been established.

Geriatric: Clinical studies of FINACEA™ Gel, 15%, did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

ADVERSE REACTIONS

In the 2 vehicle controlled, identically designed U.S. clinical studies, treatment safety was monitored in 664 patients who used FINACEA™ Gel, 15%, (N=333), or the gel vehicle (N=331), twice daily for 12 weeks.

Table 4. Cutaneous Adverse Events Occurring in ≥ 1% of Subjects in the Rosacea Trials by Treatment Group and Maximum Intensity*

	FINACEA™ Gel, 15% N=333 (100%)			Vehicle N=331 (100%)		
	Mild n=86 (26%)	Moderate n=44 (13%)	Severe n=20 (6%)	Mild N=49 (15%)	Moderate n=27 (8%)	Severe n=5 (2%)
Burning/stinging/tingling	66 (20%)	30 (9%)	12 (4%)	8 (2%)	6 (2%)	2 (1%)
Pruritus	24 (7%)	14 (4%)	3 (1%)	9 (3%)	6 (2%)	0 (0%)
Scaling/dry skin/xerosis	1 (0%)	21 (6%)	8 (2%)	33 (10%)	12 (4%)	1 (0%)
Erythema/irritation	0 (0%)	6 (2%)	6 (2%)	8 (2%)	4 (1%)	2 (1%)
Edema	3 (1%)	2 (1%)	0 (0%)	3 (1%)	0 (0%)	0 (0%)
Contact dermatitis	2 (1%)	2 (1%)	0 (0%)	1 (0%)	0 (0%)	0 (0%)
Acne	2 (1%)	1 (0%)	0 (0%)	1 (0%)	0 (0%)	0 (0%)
Seborrhea	2 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Photosensitivity	1 (0%)	0 (0%)	0 (0%)	3 (1%)	1 (0%)	1 (0%)
Skin disease	1 (0%)	0 (0%)	0 (0%)	1 (0%)	2 (1%)	0 (0%)

*Subjects may have> 1 cutaneous adverse event; thus, the sum of the frequencies of preferred terms may exceed the number of subjects with at least 1 cutaneous adverse event

FINACEA™ Gel, 15%, and its vehicle caused irritant reactions at the application site in human dermal safety studies. FINACEA™ Gel, 15%, caused significantly more irritation than its vehicle in a cumulative irritation study. Some improvement in irritation was demonstrated over the course of the clinical studies, but this improvement might be attributed to subject dropouts. No phototoxicity or photoallergenicity were reported in human dermal safety studies.

In patients using azelaic acid formulations, the following additional adverse experiences have been reported rarely: worsening of asthma, vitiligo depigmentation, small depigmented spots, hypertrichosis, reddening (signs of keratosis pilaris), and exacerbation of recurrent herpes labialis.

OVERDOSAGE

FINACEA™ Gel, 15%, is intended for cutaneous use only. If pronounced local irritation occurs, patients should be directed to discontinue use and appropriate therapy should be instituted (See **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION

A thin layer of FINACEA™ Gel, 15%, should be gently massaged into the affected areas on the face twice daily, in the morning and evening. FINACEA™ Gel, 15%, has only been studied up to 12 weeks in patients with mild to moderate rosacea (See **CLINICAL STUDIES**).

HOW SUPPLIED

FINACEA™ Gel, 15%, is supplied in tubes in the following sizes:
30 g – NDC 50419-825-01
50 g – NDC 50419-825-02

Storage

204 Store at 25ºC (77ºF); excursions permitted between 15º-30º C (59º-86ºF) [See USP Controlled Room Temperature].

205 Distributed under license; *U.S. Patent No 4,713,394*

207 Component code number

208 December 23, 2002

209 Manufactured by Schering S.p.A., Segrate, Milan, Italy

210 Distributed by:

211 Berlex Laboratories, Wayne, NJ 07470

FINACEA SAMPLE — 3 GRAM CARTON

BERLEX

Approved Masterstat

Component #7023300/2189819

Date:12/22/02Issued by: N. Thompson

Package Design and Development Department
Berlex Laboratories
300 Fairfield Road, Wayne, NJ 07470
Phone # (973) 305-5116
Fax# (973) 305-5498

Print:
Logotype and text print Pantone 2726 C Blue

Crescent shapes above and below the logo print Pantone 3272 C Green

Berlex logo prints Pantone Cool Gray C

Bar codes print black

Schering AG
Logistik P-T/PM-Layout

06.05.02

PZ/pmdr:	1310A	Stoffnr./item-no.: 2189819	ersetzt/replaces: ---
Code-Nr./code-no.:	24	Mandant/client:	44 (Italien/Italy)
Bezeichnung/name:	Finacea 3 g	Aufmachung/country:	Berlex USA
Film f r/film for	Stanzform/diecutline	Balkenfarben Version/ strip colors version:	
Textfarben/text colors:		Balkenfarbe/strip colors: PANTONE 2726 C, 3272 C, COOL GRAY C, and Black	
Farbauszug/ color separation:	schwarz/black	Farbauszug/ color separation:	
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genehmigt/ approv.:		Datum/ date:	

FINACEA SAMPLE 3 GRAM TUBE

Schering AG
Logistik P-T/PM-Layout

06.05.02

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genehmigt/ approv.:		Datum/ date:		

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FINACEA TRADE – 30 GRAM CARTON

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Component # 7023400/2189843

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Stoffnr./Item-no.:	2189843	ersetzt/replaces:	---
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Aufmachung/country:	Berlex USA		
Balkenfarben Version/ strip colors version:			
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Farbauszug/ color separation:			
alle Balkenfarben/ all strip colors:	PANTONE 2726 C, 3272 C, COOL GRAY C, and Black		
Datum/ date:			

Stanzform/diecutline

PZ/pmdr:	1307A		
Code-Nr./code-no.:	444		
Bezeichnung/name:	Finacea 30 g		
Film f./film for			
Textfarben/text colors:			
Farbauszug/ color separation:	schwarz/black		
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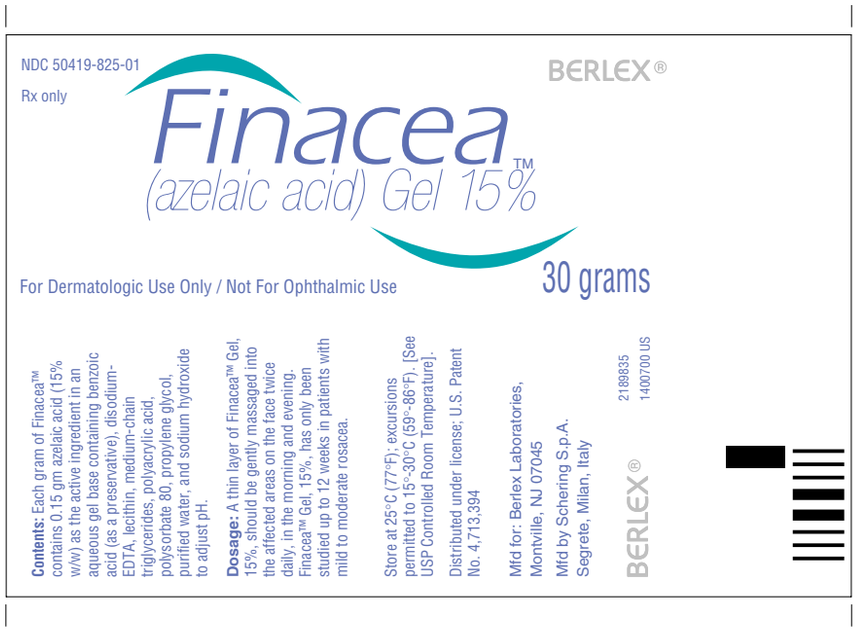
genehmigt/ approv.:			

FINACEA TRADE 30 GRAM TUBE



Schering AG
Logistik P-T/PM-Layout

06.05.02

PZ/pmdr:	**7031A**	Stoffnr./item-no.:	**2189835**	ersetzt/replaces: ---
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FINACEA TRADE –50 GRAM CARTON

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PZ/emdr.:	1307A	Stoffnr./item-no.:	2189843
Code-Nr./code-no.:	444	Mandant/client:	44 (Italien/Italy)
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alle Textfarben/ all text colors:	schwarz/black	alle Balkenfarben/ all strip colors: PANTONE 2726 C, 3272 C, COOL GRAY C, and Black	
genehmigt/ agents:		Datum/ date:	

FINACEA TRADE 50 GRAM TUBE

NDC 50419-825-02

Rx only

BERLEX®

Finacea™

(azelaic acid) Gel 15%

50 grams

For Dermatologic Use Only / Not For Ophthalmic Use

Contents: Each gram of Finacea™ contains 0.15 gm azelaic acid (15% w/w) as the active ingredient in an aqueous gel base containing benzoic acid (as a preservative), disodium-EDTA, lecithin, medium-chain triglycerides, polyacrylic acid, polysorbate 80, propylene glycol, purified water, and sodium hydroxide to adjust pH.

Dosage: A thin layer of Finacea™ Gel, 15%, should be gently massaged into the affected areas on the face twice daily, in the morning and evening. Finacea™ Gel, 15%, has only been studied up to 12 weeks in patients with mild to moderate rosacea.

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

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Mfd for: Berlex Laboratories, Montville, NJ 07045

Mfd by Schering S.p.A. Segrete, Milan, Italy

BERLEX®

2189835

1400800 US

Schering AG
Logistik P-T/PM-Layout

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PZ/pmdr:	**7031A**	Stoffnr./item-no.:	**2189835**	ersetzt/replaces: ---
Code-Nr./code-no.:	**279**	Mandant/client:	**44 (Italien/Italy)**	
Bezeichnung/name:	**Finacea 50 g**	Aufmachung/country:	**Berlex USA**	
Film f r/film for	**Stanzform/diecutline**	Balkenfarben Version/ strip colors version:		
Textfarben/text colors:		Balkenfarbe/strip colors:	PANTONE 2726 C, 3272 C, COOL GRAY C, and Black	
Farbauszug/ color separation:	**schwarz/black**	Farbauszug/ color separation:		
alle Textfarben/ all text colors:	**schwarz/black**	alle Balkenfarben/ all strip colors:	PANTONE 2726 C, 3272 C, COOL GRAY C, and Black	
genehmigt/ approv.:		Datum/ date:		

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