

BERLEX
Laboratories, Inc

NDA 21-470
FINACEA™ (azelaic acid) Gel, 15%

Page: 1 of 10

1 **FINACEA™**

2 (azelaic acid) Gel, 15%

3

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

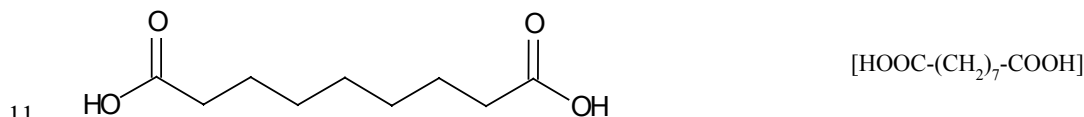
5 **Rx only**

6

7 **DESCRIPTION**

8 FINACEA™ (azelaic acid) Gel, 15%, contains azelaic acid, a naturally occurring saturated dicarboxylic acid.

9 Chemically, azelaic acid is 1,7-heptanedicarboxylic acid, with the molecular formula C₉ H₁₆ O₄, a molecular weight
10 of 188.22, and the structural formula:



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

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

17

18 **CLINICAL PHARMACOLOGY**

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

20

21 *Pharmacokinetics:* The percutaneous absorption of azelaic acid after topical application of FINACEA™ Gel, 15%,

22 could not be reliably determined. Mean plasma azelaic acid concentrations in rosacea patients treated with

23 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

24 the maximum concentration range of 24.0 to 90.5 ng/mL observed in rosacea patients treated with vehicle only.

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

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

30

31 **CLINICAL STUDIES**

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

43

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

47

48 CLEAR:

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

50 MINIMAL:

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

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52 MILD:

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

54 MILD TO MODERATE:

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

56 MODERATE:

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

58 MODERATE TO SEVERE:

59 Many papules and/or pustules, occasionally with large inflamed lesions; moderate erythema;

60 moderate degree of telangiectasia

61 SEVERE:

62 Numerous papules and/or pustules, occasionally with confluent areas of inflamed lesions;

63 moderate or severe erythema; moderate or severe telangiectasia

64

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

66 (LOCF).

67

68 Both studies demonstrated a statistically significant difference in favor of FINACEA™ Gel, 15%, over its vehicle in

69 reducing the number of inflammatory papules and pustules associated with rosacea and with success on the IGA in

70 the ITT-LOCF population at the end of treatment.

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Table 2. Inflammatory Papules and Pustules (ITT population)

	Study One	Study One	Study Two	Study Two
	FINACEA™ Gel, 15%	VEHICLE	FINACEA™ Gel, 15%	VEHICLE
	N = 164	N = 165	N = 167	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);

80

81 FINACEA™ Gel, 15%, was superior to the vehicle with regard to success based on the investigator's global
 82 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 Treatment¹

	Study One	Study One	Study Two	Study Two
	FINACEA™ Gel, 15%	VEHICLE	FINACEA™ Gel, 15%	VEHICLE
	N = 164	N = 165	N = 169	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);

83

84 **INDICATIONS AND USAGE**

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

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88

89 **CONTRAINDICATIONS**

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

92

93 **WARNINGS**

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

95

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

98

99 **PRECAUTIONS**

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

103

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

- 106
- 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.
- 107

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

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- 111 • Avoid contact of FINACEA™ Gel, 15%, with the mouth, eyes and other mucous membranes. If it does come in
112 contact with the eyes, wash the eyes with large amounts of water and consult a physician if eye irritation
113 persists.
- 114 • The hands should be washed following application of FINACEA™ Gel, 15%.
- 115 • Cosmetics may be applied after FINACEA™ Gel, 15%, has dried.
- 116 • Skin irritation (e.g., pruritus, burning, or stinging) may occur during use of FINACEA™ Gel, 15%, usually
117 during the first few weeks of treatment. If irritation is excessive or persists, use of FINACEA™ Gel, 15%,
118 should be discontinued, and patients should consult their physician (see **ADVERSE REACTIONS**).
- 119 • Avoid any foods and beverages that might provoke erythema, flushing, and blushing (including spicy food,
120 alcoholic beverages, and thermally hot drinks, including hot coffee and tea).
- 121 • Patients should report abnormal changes in skin color to their physician.
- 122 • Avoid the use of occlusive dressings or wrappings.

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

124

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

130

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

133

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

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

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

147

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

155

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

158

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

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

165

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

167

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

170 **ADVERSE REACTIONS**

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

173

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

	FINACEA™ Gel, 15%			Vehicle		
	N=333 (100%)			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%)

176 *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
177 adverse event

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178

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

184

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

188

189 **OVERDOSAGE**

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

192

193 **DOSAGE AND ADMINISTRATION**

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

197

198 **HOW SUPPLIED**

199 FINACEA™ Gel, 15%, is supplied in tubes in the following sizes:

200 30 g – NDC 50419-825-01

201 50 g – NDC 50419-825-02

202

203 **Storage**

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

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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

This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfda>
FINACEA SAMPLE 3 GRAM TUBE



Schering AG		06.05.02	
Logistik P-T/PM-Layout			
PZ/pmdr:	7025A	Stoffnr./item-no.:	2189801 ersetz/replaces: ...
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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:	
alle Textfarben/ all text colors:	schwarz/black	alle Balkenfarben/ all strip colors:	PANTONE 2726 C, 3272 C, COOL GRAY C, and Black
genehmigt/ approved:		Datum/ date:	

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Component # 1400600/2189801
Date: 12/22/02

Issued by: N. Thompson

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

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

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Schering AG Logistik P-T/PM-Layout 06.05.02	
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Code-Nr./code-no.: 444	Mandant/client: 44 (Italien/Italy)
Bezeichnung/name: Finacea 30 g	Aufmachung/country: Berlex USA
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Textfarben/text colors:	Balkenfarbe/strip colors: PANTONE 2726 C, 3272 C, COOL GRAY C, and Black
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alle Textfarben/all text colors:	alle Balkenfarben/all strip colors: PANTONE 2726 C, 3272 C, COOL GRAY C, and Black
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FINACEA TRADE 30 GRAM TUBE

NDC 50419-825-01
 Rx only

FinaceaTM
(azelaic acid) Gel 15%

BERLEX®

30 grams

For Dermatologic Use Only / Not For Ophthalmic Use

Contents: Each gram of FinaceaTM 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 FinaceaTM Gel, 15%, should be gently massaged into the affected areas on the face twice daily, in the morning and evening. FinaceaTM 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]. Distributed under license; U.S. Patent No. 4,713,394

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

2189835
 1400700 US

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Logistik P-T/PM-Layout			
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FINACEA TRADE 50 GRAM TUBE

NDC 50419-825-02
 Rx only

FinaceaTM
(azelaic acid) Gel 15%

BERLEX[®]

50 grams

For Dermatologic Use Only / Not For Ophthalmic Use

Contents: Each gram of FinaceaTM 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 FinaceaTM Gel, 15%, should be gently massaged into the affected areas on the face twice daily, in the morning and evening. FinaceaTM 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]. Distributed under license; U.S. Patent No. 4,713,394

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genehmigt/approv.:		Datum/date:	

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