

**JOHNSON FOAM FINASTERIDE FOAM WITH 5% MINOXIDIL MAXIMUM STRENGTH- zinc pyrithione aerosol, foam**  
**RapheGeneRics Corp**

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**Johnson Foam Anti-Dandruff Finasteride Foam with 5% Minoxidil Tartrate, Maximum Strength Plus Zinc Pyrithione. Evidence-Based Clinical Formulation by RapheGenerics USA.**

**Finasteride and Its Potential for the Treatment of Female Pattern Hair Loss: Evidence to Date.**

This clinical study is the original work of scientists and authors listed below, published at the National Library of Medicine, article no: PMC7060023 PMID: 32184564 Wimolsiri Iamsumang Kanchana Leerunyakul, Poonkiat Suchonwanit :

**Abstract**

The currently approved treatment for female pattern hair loss (FPHL) includes topical minoxidil administration; however, this treatment fails to achieve hair regrowth in some patients. Finasteride, a selective 5 $\alpha$ -reductase inhibitor (5-ARI), may be considered an alternative treatment.

However, due to its potential teratogenic effects, clinical studies and the use of finasteride for FPHL are limited. In this review, we aim to summarize the literature regarding the pharmacology, clinical efficacy, and adverse effects of oral finasteride for the treatment of FPHL and to provide novel therapeutic options, including topical finasteride and dutasteride, a new generation 5-ARI, for the treatment of FPHL.

Female pattern hair loss (FPHL) is a common condition in women characterized by diffuse hair thinning over the crown and parietal scalp with retention of the frontal hairline. The prevalence of FPHL increases with advancing age, affecting 50% of women during their lifetime. FPHL presents with follicular miniaturization and shortening of the anagen phase, similar to androgenetic alopecia (AGA) in men; nevertheless, the pathogenesis of FPHL remains unclear. The present understanding of the relationship between androgenic hormones and FPHL is controversial, as evidence suggests normal hormone levels in most balding females, and there is uncertainty regarding its hereditary nature.

Female pattern hair loss: hair thinning is mainly confined to the crown, with retention of the frontal hairline.

Various treatment options have been attempted to treat FPHL. The only agent approved by the US Food and Drug Administration (FDA) is topical minoxidil. Other available treatment options include low-level laser therapy, fractional laser therapy, platelet-rich plasma therapy, human follicle stem cell therapy, and hair transplantation. Nevertheless, the treatment outcome may not be satisfactory in some patients. Finasteride, an inhibitor of type II 5 $\alpha$ -reductase enzyme, is currently indicated for AGA in men. It has

been increasingly used as an off-label treatment for FPHL. Despite its potential teratogenic effects, several publications on finasteride in FPHL have shown positive results. Therefore, this review summarizes oral finasteride's pharmacology, therapeutic efficacy, and safety for treating FPHL. Furthermore, we provide novel therapeutic options, including the 5 $\alpha$ -reductase inhibitor (5-ARI) topical finasteride and oral dutasteride.

## **5% Minoxidil Clinical Studies for Women: Evidence-Based Clinical Formulation by RapheGenerics USA.**

A randomized, placebo-controlled trial of 5% and 2% topical minoxidil solutions in the treatment of female pattern hair loss

Original clinical studies were conducted by the authors listed below: Anne W Lucky, Daniel J Piacquadio, Cherie M Ditre, Frank Dunlap, Irwin Kantor, Amit G Pandya, Ronald C Savin, and Michael D Tharp. PMID: 15034503

### **Abstract**

**Background:** Topical minoxidil solution 2% stimulates new hair growth and helps stop the loss of hair in men with androgenetic alopecia and women with female pattern hair loss. Results can be variable, and historical experience suggests that higher concentrations of topical minoxidil may enhance efficacy.

**Objective:** This 48-week, double-blind, placebo-controlled, randomized, multicenter trial compared the efficacy and safety of 5% topical minoxidil with 2% topical minoxidil and placebo in treating female pattern hair loss.

**Methods:** A total of 381 women (18-49 years old) with female pattern hair loss applied 5% topical minoxidil solution (n = 153), 2% topical minoxidil solution (n = 154), or placebo (vehicle for 5% solution; n = 74) twice daily. Primary efficacy variables were change in nonvellus hair count at week 48, and patient and investigator assessments of change in hair growth/scalp coverage at week 48.

**Results:** After 48 weeks of therapy, 5% of the topical minoxidil was superior to placebo for each of the three primary efficacy measures.

The 2% topical minoxidil group demonstrated superiority over placebo for hair count and investigator assessment of hair growth/scalp coverage at 1 week 48; differences in patient assessment of hair growth at week 48 were not significantly different from placebo. The 5% topical minoxidil group demonstrated statistical superiority over the 2% topical minoxidil group in the patient assessment of treatment benefit at week 48. Both 5% and 2% topical minoxidil helped improve psychosocial perceptions of hair loss in women with female pattern hair loss. An increased occurrence of pruritus, local irritation, and hypertrichosis was observed with 5% topical minoxidil versus 2% topical minoxidil and placebo.

**Conclusion:** In this 48-week study of 381 women with female pattern hair loss, 5% topical minoxidil was superior to placebo on each of the 3 primary efficacy end points: promoting hair growth as measured by change in nonvellus hair count and patient/investigator assessments of hair growth and scalp coverage. Application of 2%

topical minoxidil was superior to placebo for assessments of nonvellus hair counts and investigator assessment of hair growth/scalp coverage at week 48; differences in patient assessment of hair growth at week 48 were not significantly different from placebo. At week 48, the 5% topical minoxidil group demonstrated statistical superiority over the 2% topical minoxidil group in the patient assessment of treatment benefit.

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Both concentrations of topical minoxidil were well tolerated by the women in this trial without evidence of systemic adverse effects. With the introduction of numerous herbal remedies for hair loss, most of which have not been tested in randomized, double-blind, In

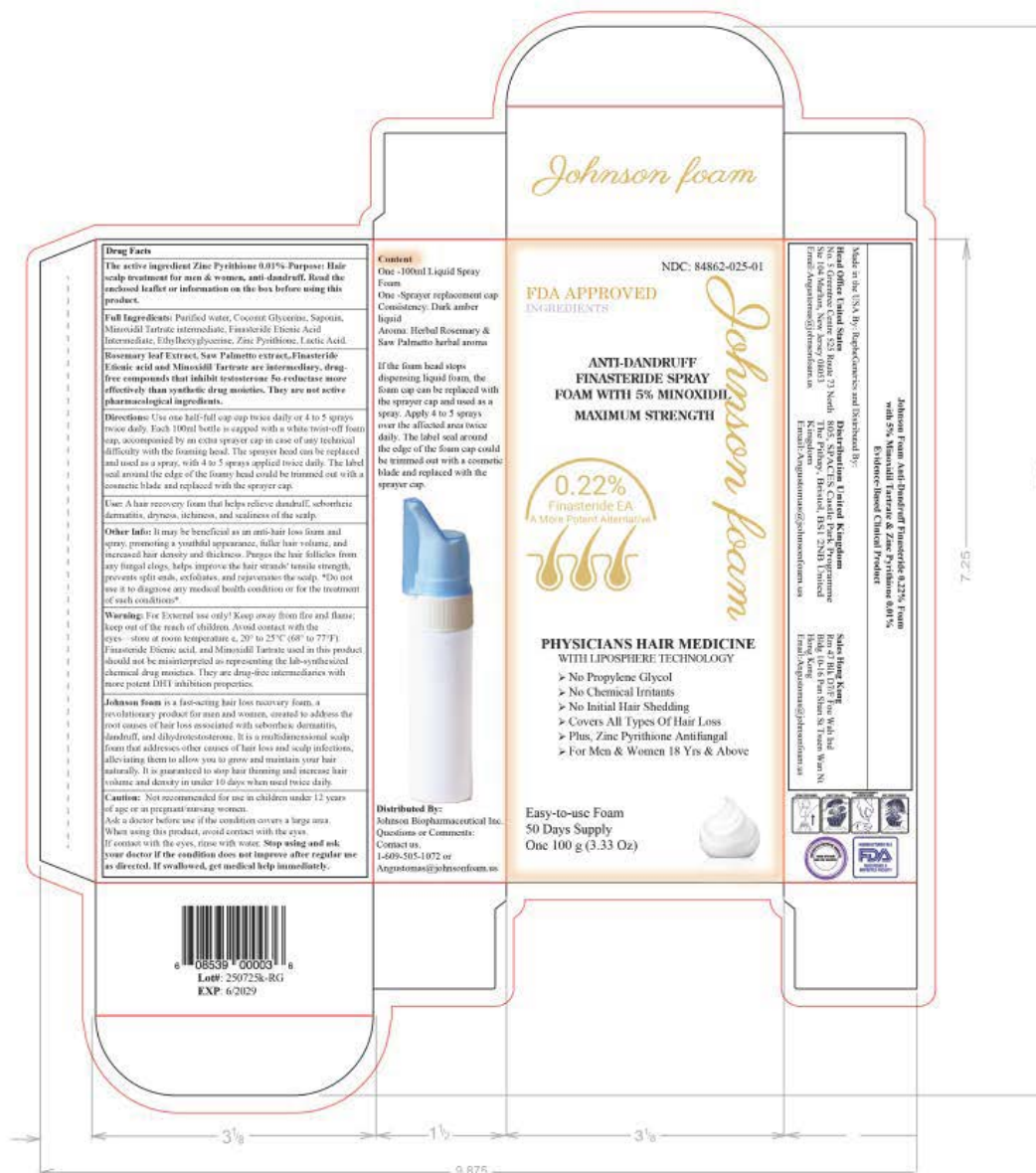
placebo-controlled trials, it is essential to describe well-controlled trials that demonstrate the efficacy and safety of topical drugs.

**Formulary Made in the USA By:** RapheGenerics Corp

Distributed By : **Johnson Biopharmaceutical Inc.**

Questions/Comments 1-609-505-1072

Email: Email:Angustomas@johnsonfoam.us



**Active ingredient:** Zinc Pyrithione 0.01% Purpose: Anti-dandruff. Uses: Temporary relief from dandruff

**Full Ingredients:** Purified water, Coconut Glycerine, Rosemary leaf extract, Saw Palmetto Extract, Saponin, Minoxidil Tartrate intermediate, Finasteride Etienic (Carboxylic)Acid Intermediate, Ethylhexyglycerine, Zinc Pyrithione.

**Directions:** Use one half-full cap cup twice daily or 4 to 5 sprays twice daily. Each 100ml bottle is capped with a white twist-off foam cap, accompanied by an extra sprayer cap in case of any technical difficulty with the foaming head. The sprayer head

can be replaced and used as a spray, with 4 to 5 sprays applied twice daily. The label seal around the edge of the foamy head could be trimmed out with a cosmetic blade and replaced with the sprayer cap.

**Warning:** For External use only! Keep away from fire and flame; keep out of the reach of children. Avoid contact with the eyes—store at room temperature 20° to 25°C (68° to 77°F).

**Other Information:** Johnson Foam is a multi-nutrition hair scalp treatment complex fortified with other ingredients proven to maintain healthy hair. Finasteride Etienic(Carboxylic) acid, and Minoxidil Tartrate used in this product should not be misinterpreted as representing the lab-synthesized chemical drug moieties. They are drug-free intermediaries with more potent DHT inhibition properties. Deep amber liquid foam spray with light brown foam appearance upon dispensing and herbal aroma

**Inactive Ingredients:** Purified water, Coconut Glycerine, Rosemary leaf Extract, Saw Palmetto Extract, Saponin, Minoxidil Tartrate intermediate, Finasteride Etienic Acid Intermediate, Ethylhexyglycerine

JOHNSON FOAM FINASTERIDE FOAM WITH 5% MINOXIDIL MAXIMUM STRENGTH			
zinc pyrithione aerosol, foam			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84862-025
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC PYRITHIONE (UNII: R953O2RHZ5) (ZINC PYRITHIONE - UNII:R953O2RHZ5)		ZINC PYRITHIONE	0.01 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
SAW PALMETTO (UNII: J7VWMH9M8QS)			
COCOLYGLYCERIDES (UNII: ISE9I7DNUG)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
WATER (UNII: 059QF0KO0R)			
MINOXIDIL TARTRATE (UNII: 70J7ZH7ECA)			5 g in 100 g
ROSEMARY (UNII: IJ67X351P9)			
FINASTERIDE CARBOXYLIC ACID (UNII: K71S04GO1T)			0.22 g in 100 g
Product Characteristics			
brown /Deep amber liquid foam spray with light brown foam appearance upon			

<b>Color</b>	brown (Deep amber liquid foam spray with light brown foam appearance upon dispensing and herbal aroma.)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84862-025-01	1 in 1 BOX	06/03/2025	
1	NDC:84862-025-02	100 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	06/03/2025	

**Labeler** - RapheGeneRics Corp (133385213)

Establishment			
Name	Address	ID/FEI	Business Operations
RapheGeneRics Corp		133385213	manufacture(84862-025)