

# TrichoFoam™ & TrichoSol™

## **Beyond Use Date Study**

**Updated June 2025** 

Alopecia is a multifactorial condition that impacts people all over the world. The incidence of the most common type of alopecia, androgenetic alopecia (AGA), is difficult to assess given the increased variability between different groups of people, but one study estimates about 50% of men will suffer from AGA by 50 years of age and up to 90% in their lifetime. In addition, by the age of 70, approximately 50% of women may suffer from AGA.<sup>1,2</sup> Alopecia areata (AA), the second most common type of alopecia, is an autoimmune disorder with a lifetime incidence of about 2% in the global population.<sup>3</sup> However, hair loss is not solely a cosmetic issue. Studies have demonstrated significant psychological impacts of hair loss such as anxiety, depression, and impaired quality of life, highlighting the importance of early treatment and management of alopecia.<sup>4</sup> Common treatments for alopecia include both oral and topical medicines. Topical medicines may allow patients to avoid systemic adverse effects associated with oral treatments. However, few topical medications for the management of AGA are currently available on the market and custom compounding may be required to achieve the correct strength and combinations. Given the need for topical alopecia therapies, stability studies validating the compatibility and stability of active pharmaceutical ingredients (APIs) in common compounding vehicles are essential.

## Why Tricho?

The Tricho vehicles all contain TrichoTech™, a patented essential oil combination that has been studied to help promote scalp health. An in vitro study of this essential oil blend noted that TrichoTech™ was found to increase expression of fibroblast growth factors (FGF-7 and FGF-10).⁵ This data is promising as some studies suggest that FGFs promote hair growth by induction of anagen phase (growth phase) in resting hair follicles.⁶ In addition to this in vitro data, there have been limited studies evaluating TrichoSol in human volunteers. One study of 20 female and male patients compared a control group (no treatment) to treatment with minoxidil 3% in a conventional alcohol vehicle, TrichoSol alone, and minoxidil 3% in TrichoSol. The study found that after 90 days of treatment all groups had increased hair in the anagen phase as compared to the control group, but an increased percentage of patients in the TrichoSol alone and TrichoSol in combination with minoxidil 3% groups were in anagen phase as compared to the minoxidil 3% in a conventional alcohol vehicle group.<sup>7</sup>

Another study evaluated TrichoSol and TrichoFoam in 59 patients via patch test. No subjects presented clinical signs of irritation, sensitization, photoallergy, or phototoxicity as a result of patch testing. Similar testing was conducted in 52 patients with other vehicles containing TrichoTechTM, including TrichoWash, TrichoCream, TrichoCond, and TrichoOil and similarly, none of the above signs of irritation or sensitization were reported as a result.<sup>8</sup>



## **Summary of Results**

#### TrichoFoam

Caffeine 0.1-2%: 180 days BUD

Clobetasol Propionate 0.01%: 150 days BUD

Clobetasol Propionate 0.1%: 14 days BUD

Dutasteride 0.1%: 90 days BUD

Dutasteride >0.1-0.25% - 30 days BUD\*

Niacinamide 0.25-0.5%: 180 days BUD

Progesterone 0.25%: 120 days BUD

Progesterone >0.25-2.5%: 90 days BUD

Minoxidil 1% through <7%: 120 days BUD</li>

Minoxidil 7%: 180 days BUD

#### TrichoSol

Cetirizine HCl 0.5-2.0%: 180 days BUD

Dutasteride 0.1%: 180 days BUD

Dutasteride >0.1%- 0.25%: 120 days BUD

Hydrocortisone acetate 0.5%: 180 days BUD

Hydrocortisone acetate >0.5 - 1%: 150 days BUD

Nicotinamide 0.25-0.5%: 180 days BUD

Progesterone 1.0%: 180 days BUD

Progesterone >1%- 2.5%: 90 days BUD

Pyridoxine HCl 0.25-5%: 180 days BUD

Minoxidil 1% through <7%: 150 days</li>

Minoxidil 7%: stability persisted up to 380 days (max allowed 180 days)

Minoxidil 2-10%, Finasteride 0.1-0.5%: 180 days BUD

Minoxidil 2-10%, Finasteride 0.1-0.5%, Fluocinolone Ac 0.01%: 180 days BUD

All preparations passed AET per USP <51> at the 180-day timepoints (individual API formulations also passed AET at T=0, and combination formulations passed AET at T=90). TrichoSol formulas were studied in amber glass containers, TrichoFoam formulas we studied in opaque PET (polyethylene terephthalate) plastic containers.

<sup>\*</sup>this product does not have limited BUD due to testing below potency, the lab was unable to test at 60 days due to formation of a precipitate



## Results

## Data in TrichoFoam<sup>9,10</sup>

	Elapsed Time		ecovery (Room	Temperature, 15-30 °C)	
API	(Days)	Low Concentration (SD)	Hq	High Concentration (SD)	рН
	0	100.00 (0.58)	2.12	100.00 (0.75)	2.11
	7	102.77 (1.44)	2.09	98.64 (1.30)	2.15
	14	104.78 (0.14)	2.15	98.69 (0.45)	2.09
	30	104.23 (0.12)	2.19	98.41 (0.12)	2.17
Caffeine	60	103.92 (0.32)	2.11	98.28 (0.18)	2.09
0.1% - 2%	90	101.95 (0.46)	1.98	97.88 (0.52)	1.99
	120	103.70 (0.36)	5.01	96.74 (0.56)	2.21
	150	103.39 (0.46)	2.17	96.47 (0.17)	2.19
	180	100.25 (0.33)	2.12	96.38 (0.65)	2.20
	0	100.00 (1.15)	4.85	100.00 (0.39)	4.30
	7	98.06 (0.49)	4.80	100.63 (0.26)	4.28
	14	95.54 (0.37)	4.77	103.09 (1.16)	4.25
Clobetasol	30	92.43 (0.42)	4.79	64.12 (0.25)	4.10
Proptionate	60	92.22 (1.01)	4.72	-	-
0.01 – 0.1 %	90	92.21 (1.09)	4.69	_	_
0.01 0.1 70	120	91.14 (0.29)	4.73	_	_
	150	90.91 (0.23)	4.69	-	-
	180	30.31 (0.23)	-	_	_
	0	100.00 (1.24)	1.98	100.00 (0.35)	2.02
	7	104.32 (1.16)	2.20	103.94 (1.26)	2.02
	14	107.72 (1.33)	2.19	100.00 (1.55)	2.20
	30	107.72 (1.89)	2.13	103.59 (1.70)	2.12
Dutasteride	60	108.08 (0.68)	2.13	103.39 (1.70)	-
0.1 - 0.25%	90	106.57 (0.59)	2.20	-	-
	120	100.57 (0.59)	-	-	-
	150	-	-	-	-
	180	-	-	-	-
	0	100.00 (0.31)	6.19	100.00 (0.31)	6.27
	7		6.01		6.10
	14	100.67 (0.36)	6.15	99.14 (0.37)	6.19
	30	101.57 (0.32)		99.76 (0.20)	5.51
Niacinamide		100.83 (0.53)	5.33	99.19 (0.76)	
0.25 - 0.5%	60	100.46 (1.33)	5.45	98.81 (0.58)	5.63
	90	99.70 (0.41)	5.53	97.81 (0.32)	5.71
	120	100.10 (0.66)	5.60	98.15 (0.42)	5.65
	150	100.04 (0.30)	5.09	98.19 (0.40)	5.15
	180	99.89 (0.81)	5.10	98.40 (0.38)	5.14
	0	100.00 (0.26)	2.04	100.00 (0.12)	1.96
	7	100.12 (0.26)	2.11	97.02 (0.74)	2.03
	14	100.00 (0.22)	2.08	91.32 (0.15)	2.00
Progesterone	30	95.10 (0.31)	2.00	91.32 (0.46)	1.97
0.25 – 2.5 %	60	94.51 (1.37)	2.20	93.11 (0.96)	2.22
	90	92.12 (1.46)	2.24	93.50 (1.37)	2.24
	120	92.69 (0.17)	2.12	88.17 (0.66)	2.19
	150	-	-	-	-
	180	400.00 (0.05)	- 2.47	- 400.00 (0.00)	- 270
	0	100.00 (0.25)	3.17	100.00 (0.33)	3.70
Minoxidil	7	100.72 (0.47)	2.74	98.09 (0.48)	3.75
	14	96.25 (0.96)	3.77	98.20 (0.20)	3.78
	30	99.92 (0.12)	3.78	101.62 (0.57)	3.79
1 – 7%	60	98.12 (0.10)	3.90	101.10 (0.51)	3.85
	90	96.90 (0.14)	3.67	101.54 (0.17)	3.64
	120	96.41 (0.14)	3.63	100.55 (0.40)	3.63
	150	85.48 (0.35)	3.69	100.59 (0.34)	3.68
	180	-	-	99.50 (1.30)	3.72

SD= Standard Deviation



Data in TrichoSol (Individual APIs)<sup>10,11</sup>

101	Elapsed Time	% Re	coverv (Room	Temperature, 15-30 °C)	
API	(Days)	Low Concentration (SD)	pH	High Concentration (SD)	рН
	0	100.00 (0.32)	4.85	100.00 (0.14)	5.03
	7	101.10 (0.15)	4.79	98.85 (0.19)	4.96
	14	100.46 (0.31)	4.81	100.25 (0.43)	4.99
	30	100.27 (0.31)	4.87	99.37 (0.43)	5.01
Cetirizine HCI	60	100.53 (0.30)	4.88	98.83 (0.48)	5.00
0.5-2%	90	99.95 (4.86)	4.86	99.23 (0.53)	5.02
	120	100.72 (0.32)	4.73	100.38 (0.45)	4.95
	150	99.28 (0.36)	4.81	102.16 (0.40)	4.99
	180	97.00 (0.94)	4.64	108.15 (0.74)	4.78
	0	100.00 (1.57)	2.25	100.00 (1.67)	2.25
	7	99.42 (1.05)	2.25	90.90 (1.67)	2.22
	14	98.67 (1.44)	2.24	100.13 (0.45)	2.23
	30	99.37 (0.10)	2.32	100.61 (0.24)	2.25
Dutasteride	60	95.17 (0.56)	2.26	101.02 (0.40)	2.20
0.1-0.25%	90	95.03 (0.99)	2.26	100.59 (0.44)	2.15
	120	94.86 (0.38)	2.25	99.55 (0.37)	2.16
	150	93.87 (0.94)	2.28	89.91 (1.61)	2.11
	180	, ,		69.91 (1.01)	2.11
	0	93.62 (1.32)	2.25 2.13	100.00 (0.37)	2.12
	7	100.00 (0.93) 100.48 (0.83)	2.13	100.00 (0.37)	2.12
	14	100.48 (0.83)	2.11	100.19 (0.56)	2.13
Hydrocerticono	30	99.94 (0.53)	2.12	100.07 (0.28)	2.12
Hydrocortisone	60	, ,			
Acetate 0.5-1.0%	90	100.81 (0.45) 100.65 (0.49)	2.23 2.33	100.71 (0.66) 99.73 (0.75)	2.18 2.45
0.5-1.0 /6	120	` '			
		103.36 (1.16)	2.38	101.15 (0.99)	2.42
	150	102.15 (0.34)	2.36	100.77 (0.23)	2.43
	180	92.83 (0.46)	2.32	100 00 (0 47)	6.05
	0 7	100.00 (0.12)	5.28	100.00 (0.47)	5.95
		101.01 (0.12)	5.26	100.00 (0.91)	
	14	101.34 (0.64)	5.30	100.00 (0.91)	6.03
Nicotinamide	30	102.64 (0.84)	5.44	100.76 (0.65)	5.34
0.25 - 0.5%	60	101.31 (0.49)	5.35	99.77 (0.32)	5.43
	90	101.48 (0.77)	5.30	98.28 (0.37)	5.49
	120	102.41 (0.37)	5.37	98.40 (0.49)	5.55
	150	101.04 (0.65)	5.00	99.43 (0.43)	5.05
	180	98.37 (0.27)	5.01 2.37	99.52 (0.70)	5.07 2.39
	0	100.00 (0.76)		100.00 (1.55)	
	7	100.39 (0.12)	2.25	97.60 (0.13)	2.34
Progesterone	14	100.16 (0.21)	2.38	91.52 (0.04)	2.37
1-2.5%	30	98.90 (0.40)	2.31	91.85 (0.54)	2.33
	60	98.09 (0.72)	2.29	91.41 (1.33)	2.32
	90	97.40 (0.82)	2.48	90.41 (1.03)	2.49
	120	98.75 (1.12)	2.46	89.46 (1.31)	2.47
	180 0	97.73 (0.33)	2.54	100.00 (4.95)	1.07
	7	100.00 (0.95) 100.98 (0.56)	2.10	100.00 (1.85) 98.19 (0.49)	1.97 2.03
		100.98 (0.56)	2.19		
	14 30	, ,	2.23	97.71 (0.12)	2.07
Pyridoxine HCI	60	101.99 (0.55)	2.21	99.23 (0.20) 97.96 (0.23)	2.05 1.96
0.25-5%	90	101.60 (0.41) 101.80 (0.44)	2.13 2.23	98.76 (0.35)	2.21
				` ,	
	120	102.89 (0.65)	2.13	99.86 (0.44)	2.29
	150	102.32 (0.30)	2.13	96.87 (1.12)	2.11
	180	103.34 (0.66)	2.14	95.21 (0.27)	1.96
	0	100.00 (0.26)	2.62	100.00 (0.16)	3.71
	7	99.36 (0.13)	2.64	100.97 (0.14)	3.74
Minoxidil	14	99.14 (0.26)	2.64	98.18 (0.32)	3.77
	30	98.03 (0.61)	2.72	100.63 (0.13)	3.78
	60	98.38 (0.37)	2.76	100.57 (0.13)	3.90
1-7%	90	95.95 (0.14)	2.72	97.28 (0.17)	3.67
	120	95.35 (0.15)	2.67	97.11 (0.18)	3.63
	150	95.41 (0.45)	2.70	98.33 (0.29)	3.69
	180	77.78 (0.84)	2.85	94.63 (1.36)	3.74
	380	-	-	97.53 (0.39)	3.79



SD= Standard Deviation

#### Data in TrichoSol (Combination Study)

Formulation	Minoxidil (%)	Finasteride(%)	Fluocinolone Ac (%)
Minoxidil 2%, Finasteride 0.1%, Fluocinolone Ac 0.01%,			
T= 0	101.5	102.7	109.6
T =60	104.5	101.3	101.2
T = 90	99.5	110.3 <sup>1</sup>	109.9
T = 120	99.0	103.9	98.0
T=180	100.5	104.9	95.5
Minoxidil 10%, Finasteride 0.5%, Fluocinolone Ac 0.01%			
T= 0	102.7	91.4	95.1
T =60	100.7	98.9	101.1
T = 90	97.5	103.9	97.6
T = 120	105.8	98.9	103.3
T=180	104.3	102.5	93.1
Minoxidil 2%, Finasteride 0.1%			
T= 0	100.0	104.8	n/a
T =60	103.5	98.7	n/a
T = 90	100.0	109.5	n/a
T = 120	102.6	106.6	n/a
T=180	101.0	105.2	n/a
Minoxidil 10%, Finasteride 0.5%			
T= 0	101.1	103.5	n/a
T =60	104.4	95.5	n/a
T = 90	101.7	107.6	n/a
T = 120	99.5%	105.9	n/a
T=180	106.5	105.5	n/a

### **Discussion**

All combinations passed AET per USP <51> at 0- and 180-day timepoints. TrichoSol formulas were studied in amber glass containers, TrichoFoam formulas we studied in opaque PET (polyethylene terephthalate) plastic containers.

#### References

- 1. Kabir Y, Goh C. Androgenetic alopecia. Journal of the Egyptian Women's Dermatologic Society. 2013;10(3):107-116. doi:10.1097/01.EWX.0000432183.50644.f6
- 2. Moravvej H, Pourani MR, Baghani M, Abdollahimajd F. Androgenetic alopecia and <scp>COVID</scp>-19: A review of the hypothetical role of androgens. Dermatol Ther. 2021;34(4). doi:10.1111/dth.15004
- 3. Miteva M, Villasante A. Epidemiology and burden of alopecia areata: a systematic review. Clin Cosmet Investig Dermatol. Published online July 2015:397. doi:10.2147/CCID.S53985
- 4. Chen S, Xie X, Zhang G, Zhang Y. Comorbidities in Androgenetic Alopecia: A Comprehensive Review. Dermatol Ther (Heidelb). 2022;12(10):2233-2247. doi:10.1007/s13555-022-00799-7



- 5. Amaral F, Jardim M, Maria de Souza Antunes V et al. In vitro effects of the Phytocomplex TrichoTech on human fibroblasts: proliferative potential and effects on gene expression of FGF-7 and FGF-10. Journal of Cosmetics, Dermatological Sciences, and Applications. 2017; 7(1): doi: 10.4236/jcdsa.2017.71001
- 6. Lin WH, Xiang LJ, Shi HX, et al. Fibroblast growth factors stimulate hair growth through β-catenin and Shh expression in C57BL/6 mice. Biomed Res Int. 2015;2015:730139. doi:10.1155/2015/730139
- 7. Pucci A, Oliveira A, Amaral F, Oliveira C. Effect of Trichosol on increasing the anagen phase of the capillary cycle of volunteers. Journal of Cosmetology and Trichology. 2019; 5(1): doi: 10.4172/2471-9323.1000139
- 8. Marianni B, Polonini H, Carolina S. Clinical Safety Profile of TrichoConcept, a Line of Cosmetic Vehicles for Personalized Treatment of Alopecia. IJPC. 2024; 28(2): 169-175
- 9. Polonini H, Lopes de Sousa P, Silva C, Marianni B. Compatibility of caffeine, clobetasol propionate, dutasteride, nicotinamide, and progesterone in TrichoFoam, a natural vehicle for hair foams. IJPC. 2024; 29(2): 161-168.
- Polonini HC, Silva CCV. Compounded Hair Solutions and Foams Containing Minoxidil: Does the Color Change Impact Stability? Scientia Pharmaceutica. 2023; 91(3):39. <a href="https://doi.org/10.3390/scipharm91030039">https://doi.org/10.3390/scipharm91030039</a>
- 11. Polonini H, Taylor S, Silva C. Compatibility of Cetirizine Hydrochloride, Dutasteride, Hydrocortisone Acetate, Nicotinamide, Progesterone, and Pyridoxine Hydrochloride in TrichoSolTM, a natural vehicle for hair solutions. IJPC. 2024: 28(5): 440-447.

**Looking for more information?** Check out the complete BUD publications in the March/April and September/October 2024 editions of IJPC. The minoxidil bracketed study is open access and may be read in it's entirely <a href="mailto:here">here</a> or reach out to the FACTS team at <a href="mailto:facts.support@fagronacademy.us">facts.support@fagronacademy.us</a>