Subjects with mild alopecia benefit from aminexil clinical 5: results of a large international observational study

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Introduction and objectives: Androgenetic alopecia in men (AGA) and female pattern hair loss (FPHL) are common hair loss causes which may heavily influence self-esteem and self-image. AGA and FPHL are caused by the heightened sensitivity of scalp follicles to dihydro-testosterone leading to dysregulation of downstream signaling cascades of inflammation. As a consequence a process of hair miniaturization develops over the time usually paralleled with a characteristic pattern distribution that varies between men and women. Histological observations showed perifollicular cells infiltrates and micro-inflammation. As this is a chronic condition, efficacy of products but also tolerability, cosmetic acceptance and patient satisfaction are key to ensure a good compliance.

The aim of this study was to assess the benefit and tolerability of Aminexil clinical 5 (AC5, containing Aminexil, Arginine, SP94, piroctone olamine and Vichy mineralizing water as active ingredients) in subjects with mild alopecia.

**Materials and methods:** This was an open-label, observational, international study conducted in real life settings in 527 adult female and male subjects with mild alopecia. At baseline subjects underwent a clinical examination including Ludwig for female and Hamilton Norwood scoring for male subjects and received AC5 to be applied once daily for a minimum of 45 days. At the end of treatment, subjects assessed their hair growth

and quality, satisfaction and local tolerance; investigators evaluated the impact of AC5 on the subjects' hair.

**Results**: Data from 421 subjects were evaluable for the efficacy analysis. Tolerability data were available for 509 subjects. 58.7% of subjects were females; the mean age was 34.1±9.1 years. Duration of hair loss was 1.3±1.8 years in women and 2.3±2.6 years, overall mean duration was 1.7±2.2 years. AC5 was used in combination with prescription treatments in 14.8% of cases (mainly topical) at inclusion with non-medical products (topicals and/or orals) in 42.2% of cases; 71.3% of women had a Ludwig score of 1 and 40.8% of males had a Hamilton Norwood score of 2.

After a mean of 82.9±17.5 days of use dermatologist evaluation rated an improvement in hair loss in 87.1% of subjects compared to baseline; it was somewhat better in women (91.8%) than in men (80.3%). Subject satisfaction on a scale from 0 (not satisfied at all) to 10 (completely satisfied) was 7.9±1.7. Tolerance was good to very good in 98.6% of subjects. The texture was considered pleasant by 95% of subjects.

**Conclusion**: In subjects with mild alopecia, AC5 reduces hair loss in both men and women with a pleasant texture. AC5 was well tolerated and highly appreciated by subjects and investigators.