



TECHNICAL DATA SHEET

1301-TDS-ENG-2023

MINOXIDIL BASE (PH.EUR.-GMP EUR)		
DESCRIPTION DCI: MINOXIDIL		DESCRIPTION DOE: MINOXIDIL
CAS Nº: 38304-91-5	EC Nº: 253-874-2	AEMPS CODE: 782A
MOL. WEIGHT: 209.25	MOL. FORMULA: C9H15N5O	ARTICLE CODE: 1301

ATTRIBUTES	SHOULD BE
Appearance	white or almost white, crystalline powder
Solubility	Slightly soluble in water, soluble in methanol and in propylene glycol
Identification B	Complies
Related substances	
Impurity E	=< 0.2 %
Impurity B	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.3 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

Minoxidil is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties

It exerts a stimulating effect on the base of the hair follicle bulb. It stimulates hair growth and slows hair loss.

It is an antihypertensive agent and peripheral vasodilator that acts by relaxing the smooth vascular musculature, mainly at the arteriolar level.

Applications

Topical route

Androgenetic alopecia In the positive treatments it is observed after 6 - 8 months of its daily use, capillary thickening, delay in the fall and, in some cases, hair growth. When the therapy ceases, the hair falls again.

Alopecia areata.

In women, it is indicated in cases of diffuse hair loss and in frontal parietal areas that present shortage of hair.



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Orally

It is administered in association with other antihypertensive drugs in the treatment of severe arterial hypertension refractory to other therapies.

Posology

In androgenetic alopecia, 1 ml of 2 - 7% solution is used every 12 hours; Apply by performing a massage. In alopecia areata, concentrations of 4-7%, 1 associated with corticosteroids and retinoids, can be used.

Side effects

The most frequent side effects are topical; irritation, contact dermatitis, hypertrichosis in front and temporal regions. Systemic effects such as hypotension and headache rarely occur.

Precautions

Topical route:

It should not be used in hypotensive people, since it can give rise to undesirable systemic effects.

It should be limited to the scalp; It should not be applied to inflamed scalp or areas affected by psoriasis, severe sunburn or severe excoriations due to the risk of increased absorption.

In women who use MINOXIDIL, the subsequent washing of the hands and face is advised to avoid possible localized hypertrichosis.

Formulation examples

Hydroalcoholic solution of MINOXIDIL

MINOXIDIL - **2 to 4 %**

Propylene glycol - **10 %**

Purified water - **20 %**

Ethanol 96 ° c.s.p. - **100 mL**

Variations in the hydroalcoholic solution of MINOXIDIL

Addition of overgreasing in solutions at 2 - 4% (prevents the usual dryness).

Addition of volatile silicones in 5% solutions (prevents the typical fat sensation of this solution).

Eliminate propylene glycol or other sensitizers.

MINOXIDIL - **3 to 4 %**

Overgreasing c.s.

Hydroalcoholic solution c.s.p. - **100 mL**

Association with other active principles

With corticoids and / or imidazoles (useful in alopecia with seborrheic dermatitis).

With corticoids and / or retinoids (useful in alopecia areata).

With vitamins, amino acids, biological extracts (useful in androgenetic alopecia).

MINOXIDIL - **2 %**

Clobetasol propionate - **0.05 %**

Tretinoin - **0.03%**

Hydroalcoholic solution c.s.p. - **100 mL**