

93796-MINOXIDIL**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation.**

Name: Minoxidil

Bulk code: 93796

1.2 Synonyms.

Minoxidilum.

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White or almost white.

3. COMPOSITION/INFORMATION ON COMPONENTS.Formula: $C_9H_{15}N_5O$

CAS: 38304-91-5

Molecular weight: 209.3 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis bulletin.

Solubility: Soluble in approximately 500 p. water, 35 p. alcohol, 23 p. methanol, 14 p. propylene glycol, 150 p. 2-propanol and 154 p. dimethyl sulfoxide. Practically insoluble in acetone, ether, chloroform, ethyl acetate, benzene, acetonitrile and petroleum ether.

Melting point: Approximately 225 °C with decomposition.

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

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

It is administered orally in combination with other antihypertensives in treatment with a beta-blocker or methyldopa to reduce the effects of cardiac acceleration and with a diuretic, such as furosemide, to control oedema. After a dose, the hypotensive peak appears after 2 - 3 hours, although in continuous therapy it may not appear for 3 - 7 days, with action persisting for up to 75 hours.

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Topically, its action mechanism is undetermined. There is a tendency to believe that it produces a vasodilation of the capillaries of the scalp and an increase in blood flow to the hair follicles which, when nourished, enter a phase of capillary stimulation, or a reduction in the growth speed of the keratinocytes, thus increasing their nutritional supply. Whatever the mechanism, it has been shown to stimulate hair growth and slow hair loss in many cases of androgenetic alopecia, when used as a solution on the scalp. In positive treatments, after 6 - 8 months of daily use, hair thickening, slowing of hair loss and in some cases hair growth can be observed. When the therapy is stopped, the hair begins to fall out again. In senile alopecia and alopecia areata there are hardly any beneficial results through use in concentrations of up to 5 %.

6. DOSAGE.

Orally: Initial doses for adults and children over 12 years of age of 5 mg daily are used, with 2.5 mg for the elderly, in one or several doses. These may be increased gradually, at intervals of no less than 3 days, to up to 40-50 mg/day, in accordance with the patient's response; in exceptional circumstances, up to 100 mg daily has been used. In children under 12 years of age, initial doses of 200 micrograms/kg of body weight/day are recommended, increasing in steps of 100-200 micrograms/kg, at intervals of more than 3 days, until blood pressure control is achieved, or up to a maximum of 1 mg/kg of body weight or 50 mg daily.

Topical use:

- In androgenic alopecia it is used as a 2 % solution, applying 1 ml twice a day.
- In senile alopecia and alopecia areata it is used in concentrations of up to 5 %.

7. REMARKS.**STORAGE:**

Store at room temperature ($25\pm 2^{\circ}\text{C}$), in hermetically sealed containers, in a dry place away from light.

On the certificate of analysis for each batch you can check whether the batch is suitable for parenteral use or not.

8. BIBLIOGRAPHY.

Monografías Farmacéuticas. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).