

SplendorTM 2% & 5%

Minoxidil BP

COMPOSITION

SplendorTM 2%: Each ml solution contains Minoxidil BP 20 mg.

SplendorTM 5%: Each ml solution contains Minoxidil BP 50 mg.

PHARMACOLOGY

Minoxidil stimulates hair growth by increasing oxygen, blood and nutrients supply to the hair follicle by widening blood vessels and inhibiting androgen hormone to affect hair follicles.

Following topical application, an average of about 1.4% of the total applied dose is absorbed from the normal intact scalp. Topical Minoxidil absorption is increased by increasing the dose applied, increasing the frequency of dosing and decreasing the barrier function of the stratum corneum. Serum Minoxidil levels and systemic effects resulting from the administration of topical Minoxidil are governed by the drug's absorption rate through the skin. Following cessation of topical dosing, approximately 95% of the systemically absorbed drug is eliminated within 4 days. Minoxidil and its metabolites are excreted principally in the urine.

INDICATION

SplendorTM is indicated for the treatment of alopecia androgenetica (hair loss) in males and females between 18 to 65 years of age.

DOSAGE AND ADMINISTRATION

SplendorTM topical solution is for external use only and should be applied when the hair and scalp are clean and dry. Apply 1 ml (7 sprays) of SplendorTM topical solution twice daily at 12-hour intervals to the scalp, beginning at the centre of the affected area and spreading the solution out to cover the entire affected area. The total daily application dose should not exceed 2 ml.

For the best results, SplendorTM topical solution should be allowed to remain on the scalp for about 4 hours before washing. The night-time application should be done 2–4 hours before going to bed to allow the solution to dry out. SplendorTM topical solution should not be massaged into the scalp, but applied lightly. A hair dryer should not be used to speed up the drying of the solution as it may decrease the effectiveness. SplendorTM topical solution should not be mixed with any hair oil. The drug should not be used more than two times a day, or be taken orally or applied to any other part of the body to avoid the risk of adverse effects and unwanted hair growth. More frequent use or longer application time have no effect on hair growth. In case of missing any daily applications of SplendorTM topical solution, the patient should continue with the next application.

Hands should be washed immediately if Minoxidil topical solution is applied with the fingertips. Clinical experience with SplendorTM indicates that twice-daily applications for 4 months or more may be required before there is evidence of hair growth. To arrest

hair fall, SplendorTM topical solution should be used for not less than 45 days. Depending upon the severity of hair loss or type and extent of baldness, particular strength of SplendorTM topical solution may be selected.

CONTRAINDICATION

- Patients with cardiac abnormalities
- Children below 18 years of age
- Patients using occlusive dressings or other medicines on the scalp
- Patients with red, inflamed infection, or irritated or painful scalp (including psoriasis & sunburn)

SIDE EFFECT

Commonly encountered side effects in clinical trials with Minoxidil topical solution were minor dermatological reactions. Dermatitis or hypertrichosis may occur. These incidences may occur in 0.1–5% of patients.

PRECAUTION

Minoxidil topical solution is more likely to cause scalp irritation. If scalp irritation continues or worsen, use of Minoxidil topical solution should be stopped.

DRUG INTERACTION

Minoxidil topical solution should not be used along with other topical agents known to alter the stratum corneum barrier such as tretinoin or dithranol, due to the enhanced absorption of Minoxidil. Although there is no clinical evidence, there exists the theoretical possibility of absorbed Minoxidil potentiating orthostatic hypotension caused by peripheral vasodilators.

USE IN PREGNANCY & LACTATION

Minoxidil topical solution should not be used during pregnancy and lactation.

STORAGE CONDITION

Store at a cool and dry place, protected from light. Keep out of the reach of the children.

HOW SUPPLIED

SplendorTM 2%: Each pack contains 60 ml solution in HDPE container.

SplendorTM 5%: Each pack contains 60 ml solution in HDPE container.

TM-Trade Mark

