Abbreviated Prescribing Information: Mintop Gain 5% and 10% solution

Composition: Minoxidil IP 5% w/v or Minoxidil IP 10% w/v, Finasteride IP 0.1% w/v. **Indications:** For the treatment of androgenic alopecia in males. **Posology and method of administration.** Clean and dry the scalp area before applying the medication. Open the cap and take the right quantity of the solution and apply on the affected scalp area with the dropper provided. Spread the solution evenly with the fingertip. Frequency of Application: 1 ml to be applied twice-daily **Contraindications:** Contraindicated in patients with hypersensitivity to minoxidil and finasteride Special Warnings and Special Precautions for Use Before using this solution, tell your doctor if you are allergic to Minoxidil or finasteride; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. If you have any of the following health problems, consult your doctor before using this product; diseases of the scalp (e.g., eczema, infection, cuts), heart problems (e.g., chest pain, heart attack, heart failure), kidney disease, liver disease. **Warnings** Drug interactions may change how the medications work or increase your risk for serious side effects. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug include: drugs for high blood pressure (e.g.,guanethidine), drugs that interact with alcohol (e.g., disulfiram, metronidazole). Symptoms of overdose may include: dizziness, drowsiness, fainting, flushing. **Special Populations** It should not be used by pregnant or nursing women. Because of the ability of type 2 5α-reductase inhibitors to inhibit the conversion of testosterone to DHT, finasteride may cause abnormalities of the external genitalia of male fetus of pregnant women who receives finasteride. No information is available on the relationship of age to the effects of topical solution in pediatric patients. Safety and efficacy have not been established for pediatric patients up to 18 years of age. Use in infants is not recommended. No information is available on the relationship of age to the effects of this medication in geriatric patients. Safety and efficacy have not been established in patients older than 65 years of age. **Adverse Effects:** Allergic reaction (reddened skin; skin rash; swelling of face) Folliculitis (acne; inflammation or soreness at root of hair) Burning, stinging, or redness at the application site may occur.Other known side effects include unwanted facial/body hair, dizziness, fast/irregular heartbeat, fainting, chest pain, swelling of hands/feet, unusual weight gain, tiredness, difficulty breathing especially when lying down. A very serious allergic reaction to this drug is rare. The frequently reported adverse events with finasteride oral administration are impotence, decrease libido, ejaculation disorders, breast enlargement or tenderness and skin rash. Physicians should instruct their patients to promptly report any changes in their breasts such as lumps, pain, or nipple discharge as breast changes including breast enlargement, tenderness and neoplasm have been reported during finasteride treatment.

Further information available on request.