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Minoxidil Topical Solution USP 2%

Minoxytop® 2%

मिनॉक्सीटॉप २%

Composition:
Each ml Contains:
Minoxidil IP.....20.0mg
Absolute Alcohol IP.....40.0%v/v
Excipients.....q.s.

In this leaflet
1. What medicine is and what is it used for.
2. What you need to know before you use this medicine.
3. How to use this medicine.
4. Possible side effects.
5. How to store this medicine.
6. Contents of the pack and other information.

Read all this leaflet carefully before you start using this medicine because it contains important information for you. Keep the leaflet: you may need to read it again.

1. WHAT MEDICINE IS AND WHAT IT IS USED FOR
Minoxidil is a medicine for topical application to the scalp that stimulates hair growth in men aged 18-65 with male-pattern hair loss (men with a family history of hair loss) and female pattern hair loss.
The start of hereditary hair loss in men is characterized by the thinning of the frontal hairline at the temples with the formation of a receding hairline. Later on, there is also increasing hair loss on the crown of the head.

You must talk to a doctor if you do not feel better or if you feel worse after 4 months

WHAT YOU NEED TO KNOW BEFORE YOU USE THIS MEDICINE
Before using this product, ask your healthcare provider if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your Health care provider for more details.

Interaction
Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your Health care provider.

Do not use Minoxytop: if you are allergic to minoxidil or any of the other ingredients of this medicine (listed in section 6)

- if you are under the age of 18 and over the age of 65
- if you are using any other medicines on the scalp
- if you have any kind of dressing or bandage on your scalp
- if you suffer from sudden or uneven hair loss.
- if you have any condition that affects your scalp, including psoriasis (an itchy inflammatory skin condition), sunburn, shaved scalp or if your scalp skin is damaged by scars or burns.
- if you have any signs of cardiovascular disease or heart rhythm problems
- if you have suffer from high blood pressure
- if you have a red, inflamed or painful scalp
- if you do not know why you are losing your hair
- if you are not sure if your hair loss is hereditary.

Warnings and precautions
Do not use this product if:
- if you have any signs of cardiovascular disease or heart rhythm problems
- if you suffer from high blood pressure
- if you are using medicines to treat high blood pressure (antihypertensive agents)

Talk to your doctor or pharmacist before using Minoxytop:
- If you have abnormal hormonal levels, a disease affecting the whole body or a lack of sufficient nutrition in the body. In these cases, your treatment may need to be adjusted
- If you are unsure whether your scalp is normal and healthy.

You should stop Minoxytop and consult a doctor
- if you are found to have low blood pressure or if one or more of the following symptoms appear: chest pain, faster heartbeat, weakness or dizziness, sudden and unexplained weight gain, swollen hands or feet, persistent redness or irritation of the scalp or if other not expected new symptoms appear.
- If effects on inner organs (systemic effects) or severe skin reactions occur, the product must be discontinued.
- Minoxytop is intended only for external use only on the scalp. Do not apply Minoxytop to other parts of the body.
- Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp. Wash your hands thoroughly before and after applying the solution and rinse other areas that have come into contact with the solution.
- Isolated cases of slight changes in hair colour have been reported by patients with very fair hair when using hair care products at the same time, or after swimming in heavily chlorinated water.
- Accidental ingestion can cause serious side effects on the cardiovascular system. Therefore, you must keep this medicine out of the reach of children.
- Avoid breathing in the spray mist.
- Minoxytop is flammable. Do not use near an open flame, lit cigarettes or some devices (e.g. hairdryers)

Children and adolescents:
- Do not give this medicine to children and adolescents below 18 years as safety and effectiveness in this age group have not been established.
- Cases of excessive hair growth on the body of infants have been reported following skin contact with minoxidil application sites of patients (caregivers) using Minoxytop. Care should be taken to ensure that children do not come into contact with areas of your body where you have applied Minoxytop topically.
- Consult a doctor if you notice excessive hair growth on the body of your child during the period you are using Minoxytop.

Other medicines and Minoxidil
- Tell your health care provider if you are taking/using, have recently taken/used or might take/use any other medicines.
- To date, no information is available on interactions between Minoxidil and other agents. Although not clinically proven, there is a

130X180 MM+BACK

theoretical possibility that absorption of the active substance in Minoxytop (minoxidil) into the body may worsen orthostatic hypotension (a drop in blood pressure felt when standing up from a lying position) in patients who are also taking peripheral vasodilators (certain high blood pressure medicines which widen the blood vessels). Guanethidine is an example of an antihypertensive drug that may interact with minoxidil.

Pregnancy and breast-feeding
- There is only limited experience with the application of Minoxidil during pregnancy. Minoxidil incorporated into the body can pass into breast milk. Thus, Minoxytop. must not be used by pregnant women and breast-feeding mothers.

Driving and using machines
This medicinal product may cause dizziness or low blood pressure. If affected, patients should not drive or operate machinery.

3. HOW TO USE THIS MEDICINE
Always use this medicine exactly as described in this leaflet or as described by your health care provider.
For spray:
1. Open the bottle and remove the seal.
2. Insert the spray applicator into the bottle.
3. Screw the spray applicator and remove the safety clip.
4. Aim the pump toward the affected area, press the pump 5 to 6 times and spread the solution with fingertips.

For dropper:
1. Open the bottle and remove the seal.
2. Insert the dropper into the bottle.
3. Take the content into the dropper to fill the volume up to 1ml line.
4. Pour the contents of the dropper aiming towards centre of the affected area of the scalp and spread evenly with fingertips.

4.POSSIBLE SIDE-EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Contact a doctor right away if you notice any of the following symptoms - you may need urgent medical treatment:
- Chest pain
- Swelling of the face, lips or throat which makes it difficult to swallow or breathe. This could be a sign of a severe allergic reaction.
- Generalised redness of the skin.
- Generalised itching.
- Tightness in the throat.
- Low blood pressure.
- Faster heartbeat.
- Weakness or dizziness.
- Sudden and unexplained weight gain.
- Swollen hands or feet.

Very common (may affect more than 1 in 10 people):
- Headache

Common (may affect up to 1 in 10 people):
- Itching
- Increased hair growth beyond the scalp (including facial hair growth in women), inflammatory skin reaction (including acneiform rash, skin rash).
- Shortness of breath, difficulty in breathing.
- Swollen arms and legs.
- Weight gain.
- High blood pressure
- Irritation of the scalp such as stinging, burning, dryness, itching, scaling, infected or inflamed hair follicles.

Uncommon (may affect up to 1 in 100 people):
- Dizziness, nausea

Rare (may affect up to 1 in 1,000 people)
- Change in hair texture may occur. If this happens, you should stop using Minoxytop.

5. HOW TO STORE THIS MEDICINE
Store at a temperature not exceeding 30°C. Preserve in tight container.
- Replace cap tightly after each use.
- Keep the medicine out of reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Minoxytop Contains:
Minoxytop Contains: Ethanol (95% v/v), Propylene glycol and Fragrance.

What Minoxytop looks like and contents of the pack
A clear colourless to pale yellow colour clear solution.
Pack Type: 60 ml HDPE Bottle along with 20 mm Micro spray pump with black over cap, HDPE black screw cap and 3 ml LDPE dropper.

Marketed by:
Healing® Pharma
Your health is our world
Healing Pharma India Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
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