
ANDROANAGEN SOLUTION

1. Generic Name

Minoxidil Topical Solution USP 5.0% w/v

2. Qualitative and quantitative composition

ANDROANAGEN SOLUTION

Composition:

Minoxidil I.P.....5.0 % w/v

Baseq. s.

The excipients used are Propanediol, Lactic water, Triethanolamine, Poly Ethyl Glycol, Glycerin, Phenoxyethanol and Ethylhexylglycerin, Melatonin, D-Panthenol, Butyl Hydro Toluene and Aloe Vera.

3. Dosage form and strength

Dosage form: Metered Dose Spray

Dosage Strength: Minoxidil I.P. 5.0% w/v

4. Clinical particulars

4.1 Therapeutic indication

ANDROANAGEN SOLUTION is indicated for the treatment of alopecia (male pattern baldness) in men.

4.2 Posology and method of administration

Posology

ANDROANAGEN SOLUTION is for topical use only. It should be used only as directed. A dose of 1 ml should be applied to the total affected areas of the scalp twice daily.

Method of administration

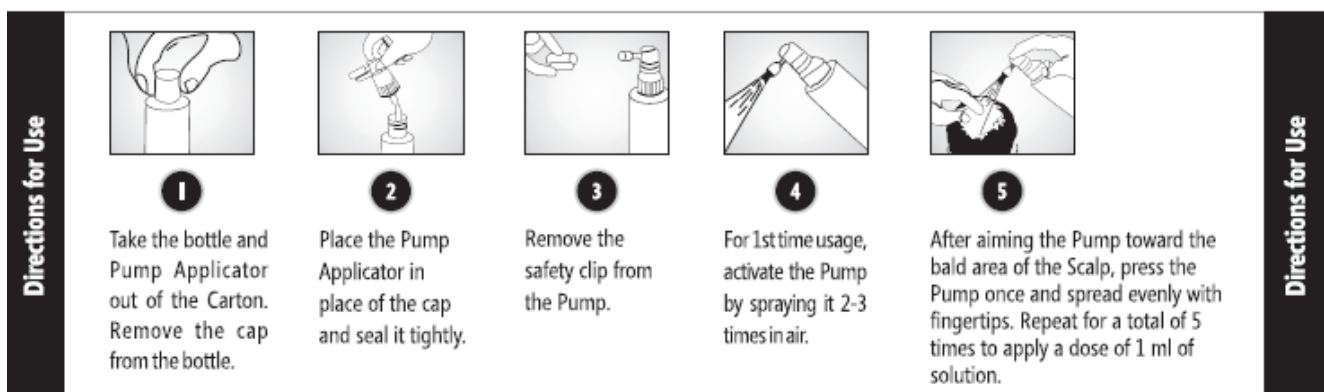
- Before application of, ANDROANAGEN SOLUTION ensure that hair and scalp are completely clean and dry.
- It is important for the complete action of the drug, the medicine reaches the scalp skin, during the time of application.
- It can be applied with the specialized spray applicator that helps to direct product onto the scalp without wastage.
- After spraying massage the scalp gently to ensure that the drug is effective.
- Apply 1 ml of ANDROANAGEN SOLUTION twice daily at 12 hours intervals to the scalp, beginning at the center 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 best results,

- ANDROANAGEN SOLUTION should be allowed to remain on scalp for at least about 4 hours before washing.

- The night time application should be done 2-4 hours before going to bed to allow the medication to dry out
- A hair dryer should not be used to speed up the drying of the solution as it may decrease the effectiveness.
- ANDROANAGEN SOLUTION should not be mixed with any other Oil or solution.
- The drug should not be used more frequently 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 will not provide any additional benefit.
- It is necessary to wash hands thoroughly after application of ANDROANAGEN SOLUTION.
- Clinical experience with Minoxidil indicated that twice daily applications for 4 months or more may be required before there is evidence of hair growth. Therefore strictly follow the advice of the physicians.

Note: Since Minoxidil Solution stimulates the growth phase in hair, the hair in resting phase will start falling off. Therefore the fall of hair in resting phase need not be a cause of concern.



4.3 Contraindications

ANDROANAGEN SOLUTION is contraindicated in the following situations:

- Patients with hypersensitivity to any of the ingredients of the formulation.
- Children below 18 years of age, pregnant women or nursing mothers.
- Hair loss of unknown reasons
- Patients with occlusive dressings or other medicines on the scalp.
- On a shaved scalp, or if there is no family history of hair loss, there is sudden and/or patchy hair loss.
- Patients with red, inflamed infection, or irritated or painful scalp (including psoriasis and sunburn)
- Patients with hypovolemic states (Ex-co-treatment with diuretics, dehydration etc.)
- Patients with hypertension, including those under treatment with antihypertensive agents, should be monitored closely and their medication adjusted if necessary, **ANDROANAGEN SOLUTION** should be used with caution in patients with any other cardiovascular disease. **ANDROANAGEN SOLUTION** should be used with caution in patients with any other cardiovascular disease.

4.4 Special warnings and precautions for use

- Although the following systemic effects have not been associated with the use of Minoxidil

Solution, there is some absorption of Minoxidil from the skin and the potential exists for systemic effects such as Tachycardia, Angina, and Edema. Patients should be monitored periodically for any systemic effects of Minoxidil.

- In the event of systemic effects, discontinue the use.
- In case of accidental contact with sensitive surfaces (such as Eyes, abraded skin and Mucous Membranes), the area should be rinsed with large amounts of cool tap water.
- It is ideal and beneficial to wash the scalp with a gentle Hair Cleanser before applying ANDROANAGEN SOLUTION.
- Hair sprays or styling products may be used on the hair while using Minoxidil Solution but for best results, it should be allowed to penetrate into the scalp before using any styling products.

4.5 Drugs interactions

Currently, there are no known drug interactions associated with the use of Minoxidil Solution. There exists the possibility of potentiating Orthostatic Hypotension in patients currently taking Guanethidine, although it has not been clinically demonstrated.

4.6 Use in special population (such as pregnant women, lactating women, pediatric patients, geriatric patients etc.)

Pregnancy and lactation

There are no well controlled trails in pregnant or lactating women treated with **ANDROANAGEN SOLUTION**. Hence, **ANDROANAGEN SOLUTION** is contraindicated in pregnant and/or lactating women.

Pediatric patients

Safety and efficacy of **ANDROANAGEN SOLUTION** in children below 18 years of age have not been established.

Geriatric patients

Safety and efficacy of **ANDROANAGEN SOLUTION** in elderly patients above 65 years of age have not been established.

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

In clinical trials with Minoxidil Topical Solution only minor dermatological reactions were observed. Local irritation was the most common side effect, including Erythema/flushing, dry skin, itching, burning sensation and rash.

Dermatitis or Hypertrichosis may occur

Infrequent adverse reactions including allergic reaction, Dizziness, Headache, tingling sensation, weakness, Oedema, eye irritation, otitis externa, visual disturbance, hair abnormalities, chest pain, alterations in pulse or Blood Pressure and Hepatitis. These indications may occur in 0.1-2 5 of patients.

Reporting of adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

4.9 Overdose

Overdosage with Minoxidil results from systemic absorption, which may occur if topical Minoxidil is applied more frequently than indicated, or if it is applied to large surface areas of the body or areas other than scalp. There is no data of Minoxidil overdosage resulting from topical administration.

Signs and symptoms of Minoxidil overdosage because of accidental ingestion or deliberate overdose would primarily be Cardiovascular effects associated with Sodium and water retention, and Tachycardia. Treatment should include Diuretic therapy to manage fluid retention and Beta-Adrenergic Blocking drugs for controlling clinically significant Tachycardia, Minoxidil and its metabolites are hemodialysable.

5. Pharmacological properties

5.1 Mechanism of Action

When applied topically, it has been shown to stimulate hair growth in individual with alopecia androgenetica (male pattern baldness) and hair loss occurring on the crown of the scalp. The mechanism by which minoxidil stimulates hair growth is not fully understood, but minoxidil can reverse the hair loss process of androgenetic alopecia by the following means:

- Increase the diameter of the hair shaft
- Stimulate anagen growth
- Prolong the anagen phase
- Stimulate anagen recovery from the telogen phase

As a peripheral vasodilator minoxidil enhances microcirculation to hair follicles. The Vascular Endothelial Growth Factor (VEGF) is stimulated by minoxidil and VEGF is presumably responsible for the increased capillary fenestration, indicative of a high metabolic activity, observed during the anagen phase.

5.2 Pharmacodynamic Properties

The hemodynamic effects of minoxidil do not correlate directly with serum levels. There is a delay in onset relative to observable serum concentrations, peak hemodynamic effects lag one hour behind peak serum concentrations, and hemodynamic effects persist long after nearly all the minoxidil has disappeared from the circulation. It appears that minoxidil requires bio activation before exerting its hemodynamic activity. The active metabolite is considered to be minoxidil sulphate. Sulfotransferase enzyme which converts minoxidil to minoxidil sulphate has been isolated from various human tissues including liver, platelets, scalp skin, hair follicles and epidermal keratinocytes. The effects of minoxidil on hair regrowth are possibly mediated by this active metabolite as well. In clinical studies, no correlation was established between serum or tissue minoxidil concentrations and hair regrowth.

5.3 Pharmacokinetic properties

Not available

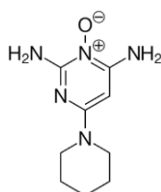
6. Nonclinical properties

Not available

7. Description

Minoxidil:

Minoxidil is 2,4-diamino-6-piperidinopyrimidine 3-oxide. The empirical formula is $C_6H_{15}N_5O$ and its molecular weight is 209.3 g/mol. The chemical structural formula is:



ANDROANAGEN SOLUTION:

Minoxidil Topical Solution is Light Yellow to Red Yellow Liquid, Transparent with characteristic odour. The excipients used are Propanediol, Lactic water, Triethanolamine, Poly Ethyl Glycol, Glycerin, Phenoxyethanol and Ethylhexylglycerin, Melatonin, D-Panthenol, Butyl Hydro toluene and Aloe Vera.

8. Pharmaceutical particulars

8.1 Incompatibilities

None

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

ANDROANAGEN SOLUTION is available in pack of 50 and 100 ml.

8.4 Storage and handing instructions

Do not store above 30°C. Store protecting from light. Do not freeze.

Keep out of reach of children.

Avoid contact with eyes.

Do not swallow.

Fortified with Melatonin.

9. Patient Counselling Information

Package leaflet: information for the patient

ANDROANAGEN SOLUTION

(Minoxidil Topical Solution USP 5.0% w/v)

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1. What **ANDROANAGEN SOLUTION** is and what it is used for?

9.2. What you need to know before you take **ANDROANAGEN SOLUTION**?

9.3. How to take **ANDROANAGEN SOLUTION**?

9.4. Possible side effects

9.5. How to store **ANDROANAGEN SOLUTION**?

9.6. Contents of the pack and other information

9.1 What **ANDROANAGEN SOLUTION** is and what it is used for?

ANDROANAGEN SOLUTION is contains Minoxidil topical solution USP 5.0%

It is indicated for the treatment of alopecia (male pattern baldness) in men.

9.2 What you need to know before you take **ANDROANAGEN SOLUTION** I?

- Before application of, **ANDROANAGEN SOLUTION** ensure that hair and scalp are completely clean and dry.
- It is important for the complete action of the drug, the medicine reaches the scalp skin, during the time of application.
- It can be applied with the specialized spray applicator that helps to direct product onto the scalp without wastage.
- After spraying massage the scalp gently to ensure that the drug is effective.
- Apply 1 ml of **ANDROANAGEN SOLUTION** twice daily at 12 hours intervals to the scalp, beginning at the center 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 best results, **ANDROANAGEN SOLUTION** should be allowed to remain on scalp for at least about 4 hours before washing.
- The night time application should be done 2-4 hours before going to bed to allow the medication to dry out
- A hair dryer should not be used to speed up the drying of the solution as it may decrease the effectiveness.
- **ANDROANAGEN SOLUTION** should not be mixed with any other Oil or solution.
- The drug should not be used more frequently 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.
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- It is necessary to wash hands thoroughly after application of **ANDROANAGEN SOLUTION**.
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Note: *Since Minoxidil Solution stimulates the growth phase in hair, the hair in resting phase will start falling off. Therefore the fall of hair in resting phase need not be a cause of concern.*

Warnings and precautions

- Although the following systemic effects have not been associated with the use of Minoxidil Solution, there is some absorption of Minoxidil from the skin and the potential exists for systemic effects such as Tachycardia, Angina, and Edema. Patients should be monitored periodically for any systemic effects of Minoxidil.
- In the event of systemic effects, discontinue the use.
- In case of accidental contact with sensitive surfaces (such as Eyes, abraded skin and Mucous Membranes), the area should be rinsed with large amounts of cool tap water.
- It is ideal and beneficial to wash the scalp with a gentle Hair Cleanser before applying

ANDROANAGEN SOLUTION.

- Hair sprays or styling products may be used on the hair while using Minoxidil Solution but for best results, it should be allowed to penetrate into the scalp before using any styling products.

Interactions with other medicines

Currently, there are no known drug interactions associated with the use of Minoxidil Solution. There exists the possibility of potentiating Orthostatic Hypotension in patients currently taking Guanethidine, although it has not been clinically demonstrated.

Pregnancy, breast-feeding and fertility

Pregnancy and lactation

There are no well controlled trails in pregnant or lactating women treated with **ANDROANAGEN SOLUTION**. Hence, **ANDROANAGEN SOLUTION** is contraindicated in pregnant and/or lactating women.

Pediatric patients

Safety and efficacy of **ANDROANAGEN SOLUTION** in children below 18 years of age have not been established.

Geriatric patients

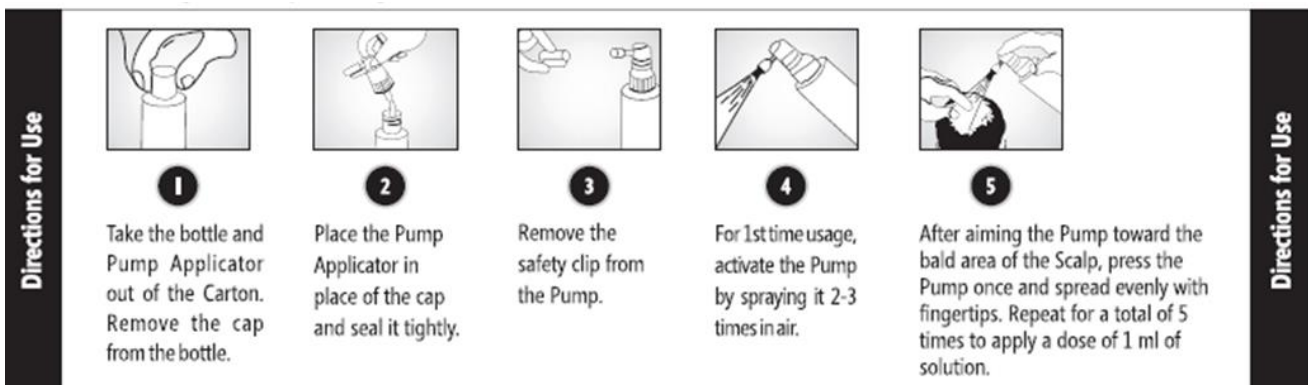
Safety and efficacy of **ANDROANAGEN SOLUTION** in elderly patients above 65 years of age have not been established.

Driving and using machines

This product may cause dizziness or hypotension. If affected, patients should not drive or operate machinery.

9.3 How to take ANDROANAGEN SOLUTION

It is important for the complete action of the drug that the medicine reaches the scalp skin, during the time of application. Due care should be taken to rub the medicine on the scalp along with application on hair.



If anyone uses too much

Seek immediate medical advice if anyone, including a child, uses too much of **ANDROANAGEN SOLUTION**. Take the container with you.

If you forget to apply a dose of the solution

If a dose is missed, **ANDROANAGEN SOLUTION** should be applied as soon as remembered, if within a few hours of the time usually applied. Do not apply if it is almost time for the next dose. If a dose is missed, the amount used in the next regular dose should not be doubled.

Children and the Elderly

Not recommended. The safety and effectiveness of ANDROANAGEN SOLUTION in users aged under 18 or over 65 has not been established.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

9.4 Possible side effects

In clinical trials with Minoxidil Topical Solution only minor dermatological reactions were observed. Local irritation was the most common side effect, including Erythema/flushing, dry skin, itching, burning sensation and rash.

Dermatitis or Hypertrichosis may occur

Infrequent adverse reactions including allergic reaction, Dizziness, Headache, tingling sensation, weakness, Oedema, eye irritation, otitis externa, visual disturbance, hair abnormalities, chest pain, alterations in pulse or Blood Pressure and Hepatitis. These indications may occur in 0.1-2.5% of patients.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting

By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store ANDROANAGEN SOLUTION

Do not store above 30°C. Store protect from light. Do not freeze.

9.6 Contents of the pack and other information

ANDROANAGEN SOLUTION is available in pack of 50 and 100 ml.

Keep out of reach of Children.

Avoid contact with eyes.

Do not swallow.

Fortified with Melatonin

10.Details of manufacturer

SunBeam Lifesciences Private Limited,

R.S. No. 23/4, Mangalam Road,

Vadamangalam, Villianur commune,

Puducherry – 605 102, India

11.Details of permission or license number with date

Mfg. Licence. No.: 17 13 4264 Issued on.: 11.09.2020

12.Date of revision

Not applicable

MARKETED BY



Torrent Pharmaceuticals Ltd.

IN/ANDROANAGEN SOLUTION/JULY-23/01/PI