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Minoxidil Tablets IP 5 / 10 mg

Minoxytop

मिनोक्सीटोप

Composition:
Each uncoated tablet contains:
Minoxidil IP.....5 mg
Excipients.....q.s.

Composition:
Each uncoated tablet contains:
Minoxidil IP.....10 mg
Excipients.....q.s.

PHARMACOLOGY

Mechanism of Action

Minoxidil lowers the elevated systolic and diastolic blood pressure by decreasing peripheral vascular resistance via vasodilation. The smooth musculature of the resistance vessels must be regarded as the site of action for the relaxant effect of minoxidil. The active metabolite of minoxidil activates the ATP-modulated potassium (K+ATP) channel causing K+ efflux, hyperpolarization, and smooth muscle relaxation.

INDICATION:

Minoxidil is indicated for the treatment of severe hypertension.

It should not be used as the sole agent to initiate therapy. It is a peripheral vasodilator and should be given in conjunction with a diuretic, to control salt and water retention, and a beta-adrenergic blocking agent, or appropriate substitute, to control reflex tachycardia.

CONTRAINDICATIONS:

Hypersensitivity to the active substance or to any of the excipients.

Minoxidil is contra-indicated in patients with a phaeochromocytoma because it may stimulate secretion of catecholamines from the tumour through its antihypertensive action.

WARNING AND PRECAUTIONS:

Salt and water retention

If used alone, minoxidil can cause a significant retention of salt and water leading to physical signs such as oedema, and to clinical deterioration of some patients with heart failure. Diuretic treatment alone, or in combination with restricted salt intake is, therefore, necessary for all patients taking minoxidil. Haemodilution may occur leading to temporary decrease in haematocrit, haemoglobin, and erythrocyte count (by approximately 7% initially which then recovers to pre-treatment levels). The patient's bodyweight, fluid and electrolyte balance should be monitored for evidence of fluid retention.

Renal failure or dialysis patients

Those patients with renal failure or on haemodialysis may require smaller doses of minoxidil (see section 4.2).

Myocardial infarction

Patients who have had myocardial infarction should only be treated with minoxidil after a stable post-infarction state has been established.

Tachycardia

Because minoxidil is a vasodilator, reflex tachycardia may occur and possibly angina pectoris may occur in patients at risk; it is recommended that minoxidil be used in combination with beta-adrenergic blocking agent or other sympathetic nervous system suppressants to blunt or prevent such a response.

Hypertrichosis

Hypertrichosis occurs in most patients treated with minoxidil and all patients should be warned of this possibility before starting therapy. Most patients will experience an elongation, thickening and enhanced pigmentation of fine body hair. Usually these signs will emerge 3 to 6 weeks after starting treatment.

ECG alterations

Soon after starting minoxidil therapy approximately 60% of patients exhibit ECG alterations in the direction and magnitude of their T waves. Large changes may encroach on the ST segment, unaccompanied by evidence of ischaemia.

Thrombocytopenia and leucopoenia

Thrombocytopenia and leucopoenia have been rarely reported.

Pericarditis, Pericardial Effusion and Tamponade

Pericarditis, Pericardial Effusion and Tamponade – Although there is no evidence of a causal relationship, there have been multiple reports of pericarditis occurring in

association with minoxidil.

Paediatric population

Children strictly require appropriate and individualised dosing of minoxidil, beta-blockers and diuretics. They should be under close specialist supervision in hospital. Caution is required when there is significant renal impairment.

SIDE EFFECTS:

- Excessive hair (Hypertrichosis)
- Temporary shedding
- Ankle swelling and fluid retention
- Low blood pressure and feeling light headed
- Fast heart rate
- Headaches
- Uncommon side effects include – nightmares, insomnia, pericarditis, skin rashes, nausea, vomiting, breast tenderness

INTERACTIONS:

The effect of minoxidil may be additive to concurrent antihypertensive agents and other agents with blood pressure lowering effects. The interaction of minoxidil with sympathetic-blocking agents such as guanethidine or betanidine may produce excessive blood pressure reduction and/or orthostatic hypotension.

If possible guanethidine should be discontinued well before minoxidil is begun. If this is not feasible, minoxidil therapy should be instituted in the hospital and the patient monitored carefully for orthostatic events.

DOSAGE AND ADMINISTRATION:

The recommended starting dose is 5 mg per day. If required, this dosage can later be increased up to 20 mg, and then to 40 mg daily (given as a single dose or in two divided doses). Dose increases should be made at increments of 5 mg to 10 mg minoxidil per day at intervals of three or more days. If a dose of 50 mg of minoxidil has been reached, the dose may be increased by 25 mg minoxidil per day to a maximum dose of 100 mg per day.

Method of Administration

Oral administration

OVERDOSAGE:

If exaggerated hypotension is encountered, it is most likely to occur in association with residual sympathetic nervous system blockade (guanethidine-like effects or alpha-adrenergic blockade). Recommended treatment is intravenous administration of normal saline. Sympathomimetic drugs, such as noradrenaline (norepinephrine) or adrenaline (epinephrine), should be avoided because of their excessive cardiac-stimulating action. Phenylephrine, angiotensin II and vasopressin, which reverse the effect of minoxidil, should be used only if inadequate perfusion of a vital organ is evident.

STORAGE:

Store protected from light & moisture at a temperature not exceeding 30°C.

Keep the medicine out of reach of children.

PRESENTATION:

Pack the 5 Strips of 10 tablets in one carton with Insert.

Manufactured By:

Healing® Pharma
Your health is our world

Healing Pharma India Pvt. Ltd.
(An ISO 9001-2015 Certified Company)

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