

Oxifyl[®] CR

Pentoxifylline BP 400 mg

Composition:

Each controlled release tablet contains Pentoxifylline BP 400 mg.

Mode of Action:

Pentoxifylline and its metabolites improve the flow properties of blood by decreasing its viscosity. In patients with chronic peripheral arterial disease, this increases blood flow to the affected microcirculation and enhances tissue oxygenation. The precise mode of action of pentoxifylline and the sequence of events leading to clinical improvement are still to be defined. Pentoxifylline administration has been shown to produce dose-related hemorrhheologic effects, lowering blood viscosity, and improving erythrocyte flexibility. Leukocyte properties of hemorrhheologic importance have been modified in animal and in vitro human studies. Pentoxifylline has been shown to increase leukocyte deformability and to inhibit neutrophil adhesion and activation. Tissue oxygen levels have been shown to be significantly increased by therapeutic doses of pentoxifylline in patients with peripheral arterial disease.

Indications:

Oxifyl[®] CR tablet is indicated for the treatment of peripheral vascular disease evident as intermittent claudication, venous leg ulcers, Oxifyl[®] CR tablet can improve function and symptoms but is not intended to replace more definitive therapy, such as surgical bypass, or removal of arterial obstructions when treating peripheral vascular disease.

Dosage and administration:

The usual dosage of Oxifyl[®] CR tablet is one tablet (400 mg) two to three times a day with meals. While the effect of Oxifyl[®] CR tablet may be seen within 2 to 4 weeks, it is recommended that treatment be continued for at least 8 weeks. Digestive and central nervous system side effects are dose related. If patients develop these effects it is recommended that the dosage be lowered to one tablet twice a day (800 mg/day). If side effects persist at this lower dosage, the administration of Oxifyl[®] CR tablet should be discontinued.

Contraindications:

Pentoxifylline should not be used in patients with recent cerebral and/or retinal hemorrhage or in patients who have previously exhibited intolerance to this product or methylxanthines such as caffeine, theophylline, and theobromine.

Precautions:

Patients on warfarin should have frequent monitoring of prothrombin times, while patients with other risk factors complicated by hemorrhage (e.g., recent surgery, peptic ulceration, cerebral and/or retinal bleeding) should have periodic examinations for bleeding including, hematocrit and/or hemoglobin.

Side-effects:

Cardiovascular - dyspnea, edema, hypotension. Digestive - anorexia, cholecystitis, constipation, dry mouth/thirst. Nervous - anxiety, confusion, depression, seizures. Respiratory - epistaxis, flu-like symptoms, laryngitis, nasal congestion. Skin and Appendages - brittle fingernails, pruritus, rash, urticaria, angioedema. Special Senses - blurred vision, conjunctivitis, earache, scotoma. Miscellaneous - bad taste, excessive salivation, leukopenia, malaise, sore throat/swollen neck glands, weight change.

Drug interactions:

Patients on warfarin should have frequent monitoring of prothrombin times, while patients with other risk factors complicated by hemorrhage (e.g., recent surgery, peptic ulceration) should have periodic examinations for bleeding including hematocrit and/or hemoglobin. Concomitant administration of Pentoxifylline and theophylline-containing drugs leads to increased theophylline levels and theophylline toxicity in some individuals. Such patients should be closely monitored for signs of toxicity and have their theophylline dosage adjusted as necessary. Pentoxifylline has been used concurrently with antihypertensive drugs, beta blockers, digitalis, diuretics, antidiabetic agents, and antiarrhythmics, without observed problems. Small decreases in blood pressure have been observed in some patients treated with Pentoxifylline; periodic systemic blood pressure monitoring is recommended for patients receiving concomitant antihypertensive therapy. If indicated, dosage of the antihypertensive agents should be reduced.

Use in pregnancy and lactation:

Pentoxifylline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pentoxifylline and its metabolites are excreted in human milk. Because of the potential for tumorigenicity shown for pentoxifylline in rats, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric use:

Safety and effectiveness in pediatric patients have not been established.

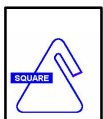
Storage condition:

Store in a cool and dry place. Protect from light and moisture.

How supplied:

Oxifyl® CR: Box containing 3X10 controlled release tablets in Alu-Alu strip.

Manufactured by :



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