Stroke
A Journal of Cerebral Circulation

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In clinical trials, adverse effects were relatively frequent (over 50%). Most were mild, but 21% of patients taking Ticlid discontinued therapy. The most serious adverse effect was neutropenia/agranulocytosis, which may be life threatening (see Warnings). CBC monitoring is required at baseline and then every 2 weeks for at least the first 3 months of therapy.

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Brief Description

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INDICATIONS AND USAGE TICUD is indicated to reduce the risk of thrombotic stroke (first or recurrent) in patients with a previous transient ischemic attack (TIA) or completed stroke, who are at high risk for subsequent stroke. (See INDICATIONS AND USAGE) In patients at high risk for recurrent stroke, TICUD has been shown to reduce the risk of recurrent stroke. In clinical trials, TICUD was better than aspirin in reducing the risk of subsequent stroke, with or without TICUD. (See ADVERSE REACTIONS)

Neutropenia defined in these studies as an ANC < 1000 neutrophils/mm³ occurred in 5 of 50, 2.0%. Severe Neutropenia (<450 neutrophils/mm³): In the 22 patients, the neutrophilia was transient and did not require discontinuation of therapy. The clinical significance of this finding has not been determined. It may be related to the thienopyridine structure of TICUD, since no such events have been reported with aspirin or placebo. There were no cases of neutropenia in the clinical trials with TICUD. In addition, the incidence of neutrophilia was not increased in patients with a previous history of neutropenia.

Thrombocytopenia: Rarely, thrombocytopenia may occur in isolation or together with neutropenia. If clinical evaluation and laboratory studies confirm the presence of thrombocytopenia (<30,000 cells/mm³), the drug should be discontinued. Cholesterol Elevation: TICUD therapy causes an increase in serum cholesterol and triglycerides. Serum total cholesterol levels are increased 8-10% within one month of therapy and persist at that level. The risk of the lipoprotein subfractions are increased. Other Hematological Effects: Thrombocytopenia and thrombocytopenic purpura, some of which have been fatal, have been reported in Post-Marketing Surveillance. Anticoagulant Drugs: The tolerance and safety of concomitant therapy with TICUD and warfarin have not been established. In controlled studies, TICUD therapy has been associated with a 30% increase in the plasma half-life of antipyrine and may potentiate the effect of aspirin. Also, there is an increased risk of severe bleeding in patients who are taking both TICUD and warfarin. (See Warnings) Preparations in which TICUD is not indicated to help prevent recurrent stroke

In controlled clinical trials, the incidence of neutrophilia was not increased in patients with a previous history of neutropenia. However, there were no cases of neutropenia in the clinical trials with TICUD. In addition, the incidence of neutrophilia was not increased in patients with a previous history of neutropenia.
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