

The Right Fit for Lipid Control

Important Safety Information about ANTARA

ANTARA is indicated as adjunctive therapy to diet to reduce elevated Total Cholesterol (Total-C), LDL-C, triglycerides, and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa and IIb). ANTARA is also indicated as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia (Fredrickson Types IV and V hyperlipidemia).

Important Safety Considerations: The effect of ANTARA on coronary heart disease morbidity and mortality and noncardiovascular mortality has not been established. ANTARA is contraindicated in patients with hypersensitivity to fenofibrate, in patients with hepatic or severe renal dysfunction including primary biliary cirrhosis, in patients with unexplained persistent liver function abnormality, and in patients with preexisting gallbladder disease. There are no adequate and well-controlled studies in pregnant women and should be used during pregnancy only if the potential benefit justifies the potential risk to fetus. ANTARA should not be used in nursing mothers. Safety and efficacy in pediatric patients has not been established. The combined use of ANTARA and HMG-CoA reductase inhibitors should be avoided unless the benefit of further alterations in lipid levels is likely to outweigh the increased risk of this drug combination. The most common side effects are: abnormal liver function tests, including increased AST; increased ALT; CPK increase; respiratory disorder; abdominal pain; back pain; headache; diarrhea; nausea; rhinitis; asthenia; flu syndrome and constipation.

Please see full Prescribing Information.

References: 1. Data on file (A-005). Oscient Pharmaceuticals Corporation. 2. Overgaard ABA, Højsted J, Hansen R, Møller-Sonnergaard J, Christrup LL. Patients' evaluation of shape, size and colour of solid dosage forms. *Pharm World Sci.* 2001;23(5):185-188.





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