Each NACSY tablet for oral administration contains the following inactive ingredients: croscarmellose sodium, hypromellose, magnesium stearate, and microcrystalline cellulose.

Clinical Pharmacology

The clinical efficacy of niacin in LDL cholesterol levels is supported by both epidemiologic and clinical trials and by meta-analyses. In addition, niacin decreases total cholesterol, triglycerides, and triglyceride levels (LDL reduction is not known for coronary heart disease). The SSS (Secondary Prevention Study) demonstrated that 500 mg/day of niacin in 162 non-smoking males with previous coronary bypass surgery reduced the primary, per subject cardiac event rate in men 30 to 64 years old with a history of myocardial infarction or with coronary artery disease. A significant increase in total HDL is associated with a shift in the distribution of plasma lipids and lipoproteins away from atherogenic towards a more favorable pattern. The increase in total HDL is associated with a shift in the distribution of plasma lipids and lipoproteins away from atherogenic towards a more favorable pattern. The increase in HDL is associated with a shift in the distribution of plasma lipids and lipoproteins away from atherogenic towards a more favorable pattern.

Mechanism of Action

The mechanism by which niacin exerts these effects is not entirely understood, but may involve several actions, including a decrease in the production or release of triglyceride-laden very low-density lipoprotein (VLDL) particles, an increase in the fractional catabolic rate of VLDL, a reduction in the production of triglyceride-rich lipoprotein particles, and a decrease in the fractional catabolic rate of low-density lipoprotein (LDL) particles. These actions result in a decrease in the rate of VLDL production and an increase in the rate of VLDL catabolism, leading to a decrease in the levels of total cholesterol, triglycerides, and LDL cholesterol. The increase in HDL cholesterol is associated with a shift in the distribution of plasma lipids and lipoproteins away from an atherogenic pattern towards a more favorable pattern.

Adverse Reactions

Liver Dysfunction

Cases of severe hepatic toxicity, including fulminant hepatic necrosis, have occurred in patients who have substituted sustained-release, extended-release, or modified-release niacin products for immediate-release (crystalline) niacin at equivalent doses. Liver dysfunction, including severe hepatic necrosis, has been reported rarely in patients treated with sustained-release or modified-release forms of niacin. Patients who consistently have total serum or plasma triglycerides below 1000 mg/dL are unlikely to develop hepatic dysfunction.

Hypotension

Hypotension, including drug-induced hypotensive reactions, has been reported rarely in patients treated with sustained-release or modified-release forms of niacin. Hypotensive reactions are uncommon in patients treated with immediate-release (crystalline) niacin products. Hypotension has been reported rarely in patients treated with sustained-release or modified-release forms of niacin. Hypotensive reactions are uncommon in patients treated with immediate-release (crystalline) niacin products.

Niacin is a nicotinic acid, a water-soluble vitamin that is an essential component of the coenzyme complex and an important component of the pyridine and nicotinamide coenzymes. Niacin is an antihyperlipidemic agent, a component of the coenzyme complex, and a precursor of the vitamin niacinamide.

Pharmacokinetics

The plasma elimination half-life of niacin ranges from 20 to 45 minutes. Niacin has a short plasma elimination half-life.

Indications and Usage

Cholesterol and triglyceride lowering with niacin is indicated for the management of adults with Types IIb (chylomicronemia) or Type III (hyperchylomicronemia) hyperlipidemias and for the treatment of adults with a 20% or greater risk for coronary heart disease who are unable to achieve therapeutic goals on diet alone. Niacin is also indicated for the treatment of adult patients with very high serum triglyceride levels (Types IV and V hyperlipoproteinemia) and who have normal levels of VLDL. Inspection of plasma refrigerated for 14 hours is helpful in distinguishing Types I, IIa, and IIb.

Niacin is also indicated as adjunctive therapy for the treatment of adult patients with very high serum triglyceride levels (Types IV and V hyperlipoproteinemia) and who have normal levels of VLDL. Inspection of plasma refrigerated for 14 hours is helpful in distinguishing Types I, IIa, and IIb.

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2. MANUFACTURED BY:  

3. REFERENCES  

4. SUPPORTIVE MEASURES  

5. PREGNANCY  

6. SAFETY AND EFFECTIVENESS IN CHILDREN AND ADOLESCENTS HAVE NOT BEEN ESTABLISHED.