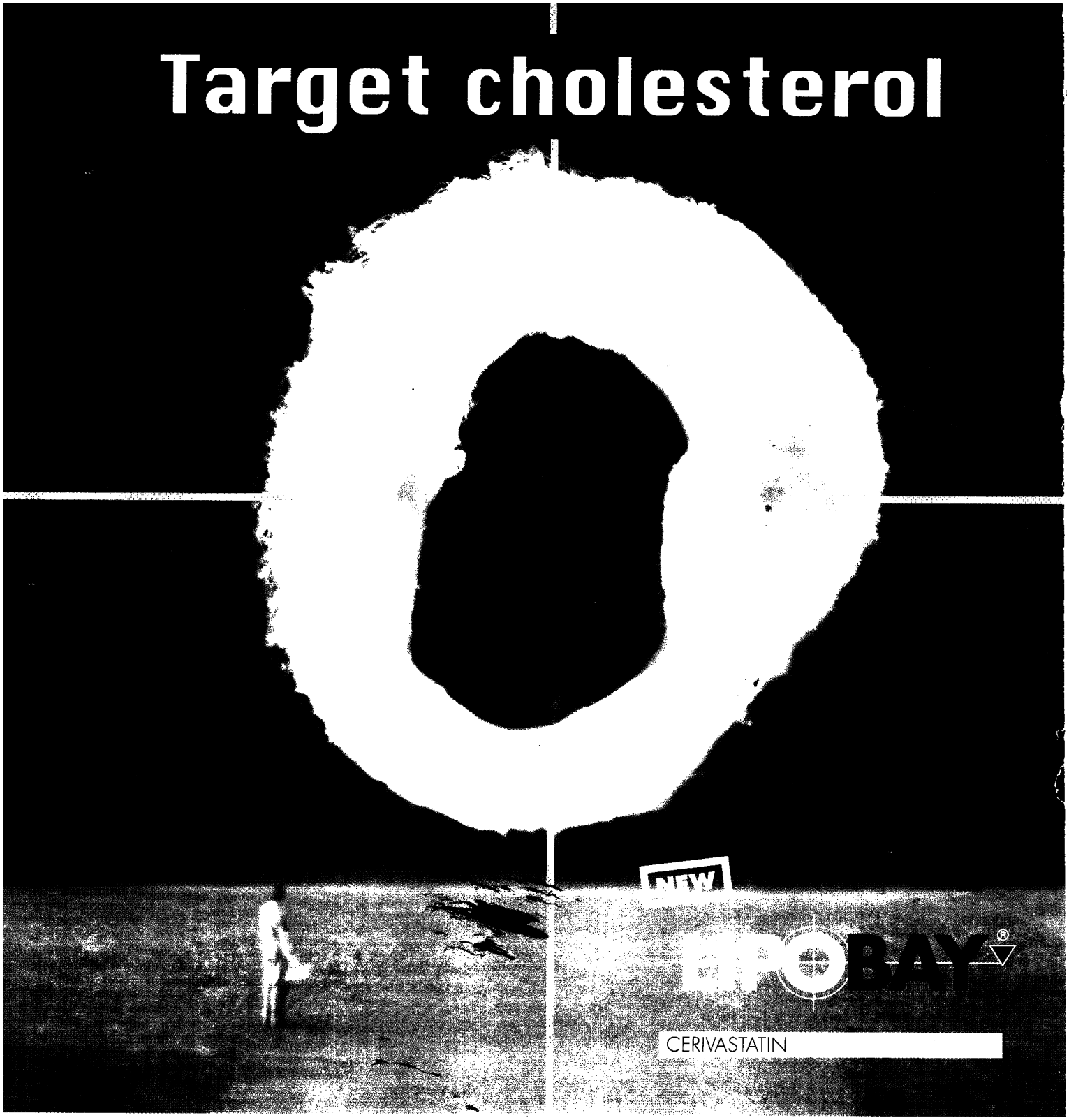
Target cholesterol



ABRIDGED PRESCRIBING INFORMATION ▼
LIPOBAY® (100 Microgram Tablets)
LIPOBAY® (200 Microgram Tablets)
LIPOBAY® (300 Microgram Tablets)
(Refer to Summary of Product Characteristics before prescribing)
Qualitative and quantitative composition: Tablets each containing 100, 200 or 300 micrograms cerivastatin. **Pharmaceutical form:** Tablets for oral administration. **Therapeutic indications:** Primary hypercholesterolaemia (Types IIA + IIB); The treatment of hypercholesterolaemia in patients who have not responded adequately to an appropriate diet. **Posology and method of administration:** Exclude secondary causes of hypercholesterolaemia prior to therapy. Continue patients on their standard cholesterol-lowering diet during treatment. ***Adults:*** Take once a day in the evening (at dinner or bed time). The initial dose is 100mcg once-daily. At intervals of at least four weeks, dosage may be increased by increments of 100mcg depending on response. The maximum recommended dose is 300mcg once-daily. Administration with food has no influence. A response is seen within two weeks and the maximum therapeutic response occurs within four weeks, which is maintained during continuation of therapy. ***Elderly:*** Treatment should be initiated at the lower end of the dosage range. ***Renal impairment:*** Initiate treatment at a once-daily dose of 100mcg in moderate to severe renal disease. Subsequent titration, up to a maximum dose of 200mcg once-daily should be performed with caution. ***Children:*** Not recommended. **Concomitant administration:** Efficacy may be enhanced when combined with a bile-acid sequestrant (e.g. cholestyramine). **Contra-indications:** Hypersensitivity to any component of Lipobay®; hepatic impairment or unexplained, persistent elevations in serum transaminases; pregnancy, lactation or women of childbearing potential unless adequately protected by non-hormonal contraceptive methods. **Special warnings and precautions for use:** ***Liver function:*** Increases in liver enzymes have occurred during therapy, the majority of cases being minor and asymptomatic. Liver function tests should be performed before treatment begins and periodically thereafter. Discontinue therapy if increases in ALT and AST exceed three times the upper limit of normal (ULN). Caution in patients with a history of heavy alcohol ingestion or a past history of liver disease (active liver disease or unexplained transaminase elevations are contra-indications). ***Muscle:*** Sporadic elevations of creatine phosphokinase (CPK) have been observed, usually of no clinical significance. Rarely, myopathy, associated with marked elevations of CPK (≥10 times the ULN) and/or with diffuse myalgias, muscle tenderness or weakness, has been reported with HMG-CoA reductase inhibitors. Muscle pain, tenderness or weakness should be reported by patients promptly especially if accompanied by malaise or fever. Discontinue if markedly elevated CPK levels occur, or if myopathy is diagnosed or suspected. Risk of myopathy is known to increase in those patients receiving HMG-CoA reductase inhibitors who are concomitantly treated with cyclosporin, fibric acid derivatives and nicotinic acid. Rare cases of renal dysfunction secondary to rhabdomyolysis have occurred with drugs of this class. Therapy with Lipobay® should be temporarily withheld in any patient experiencing a condition pre-disposing to the development of renal failure secondary to rhabdomyolysis. ***Ophthalmological:*** As with some other statins, new subcapsular and nuclear opacities have been reported, although a causal relationship with Lipobay® has not been established. **Interaction with other medicaments and other forms of interaction:** Bile a sequestering agents: Lipobay® should be administered at least hours after the resin (e.g. cholestyramine). No clinically signifi effects were seen with warfarin, digoxin, antacids, cimetidine. ***Effe on ability to drive and use machines:*** None known. **Undesira effects:** Increase in incidence over placebo: headache, up respiratory tract symptoms (including rhinitis, sinusitis, increa cough), flu syndrome, arthralgia, back pain, abdominal pain, mya and insomnia. **Legal category:** POM. **Package quantities and ba NHS costs:** Calendar packs containing 28 tablets; Lipobay® Microgram Tablets £12.95, Lipobay® 200 Microgram Tablets £17 Lipobay® 300 Microgram Tablets £18.20 **Marketing Authorisa numbers:** 00010/0226-0228.
Date of Preparation: February 1997

Bayer

For further information refer to
Summary of Product Characteristics or contact:
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