

DATA SHEET

OLBETAM[®]

Acipimox 250mg capsules

Presentation

Gelatin capsule shell, self-locking, red cap, red brown body, opaque, size No. 1.

Uses

Actions

OLBETAM inhibits the release of non esterified fatty acids from adipose tissue and reduces total serum triglyceride and cholesterol levels. These decreases occur in the very low density lipoprotein (VLDL) fraction and in the low density lipoprotein (LDL) fraction. In addition, OLBETAM increases high density lipoprotein (HDL) cholesterol.

Pharmacokinetics

OLBETAM is rapidly and almost completely absorbed from the gastrointestinal tract, reaching peak plasma levels within two hours after oral administration. The elimination half life is about two hours. Binding to plasma proteins is negligible. The drug is not significantly metabolized in humans and is eliminated by the urinary route.

LD50 values in mice and rats range from 2000 to 5000mg/Kg, while doses up to 5000mg/Kg are tolerated in dogs. No target organ can be identified in rats under chronic treatment at doses up to 2700mg/Kg/day, the only clear-cut dosage effect being a reduction of body weight; in particular, there is no evidence of hepatic peroxisome proliferation, liver enlargement or lens opacities. Dogs treated with doses up to 800mg/Kg/day for 1 year show only sporadic dose-dependent emesis, but no other toxicity. Several tests, including the Ames, DNA repair, chromosome aberration and micronucleous did not reveal any mutagenic potential. There is no evidence of teratogenicity or carcinogenicity in the species tested. *In vitro* and *in vivo* tests, carried out to evaluate the allergenic potential failed to identify any sensitising capacity of the compound.

Indications

OLBETAM is indicated for the treatment of lipid disorders characterised by elevated plasma levels of triglycerides (Fredrickson Type IV hyperlipoproteinaemia), or both triglycerides and cholesterol (Type IIb hyperlipoproteinaemia).

OLBETAM should be prescribed only for patients with lipid or lipoprotein abnormalities demonstrated by laboratory tests and where diet alone is insufficient to correct the condition.

Dosage and Administration

The recommended dosage is one 250mg capsule 2 or 3 times daily to be taken with or after meals. The lower dose is advised in Type IV and the higher in Type IIb hyperlipoproteinaemia.

In patients with renal impairment it is advisable to reduce the dosage on the basis of creatinine clearance values:

Clearance between 80 and 40mL/min - 250mg once daily.

Clearance between 40 and 20mL/min - 250mg every other day.

It is not recommended that OLBETAM be administered to children.

Contraindications

Confirmed individual hypersensitivity to OLBETAM.

Peptic ulcer.

Severe Renal Impairment.

Warnings and Precautions

Before instituting OLBETAM therapy, attempts should be made to control serum lipids with appropriate diet, exercise and weight loss in case of obesity. Since long-term administration of OLBETAM is recommended, all baseline values, including lipid profile, should be measured before treatment and periodic determinations of serum lipids should be obtained to confirm that the desired therapeutic effect has been achieved.

In case of dyslipidaemia associated with non insulin dependent diabetes, OLBETAM effectively lowers serum lipids without adversely affecting and often improving overall glycaemic control.

Evidence of clinical efficacy in the prevention of heart disease has not been established.

Pregnancy and Lactation

Safe use in human pregnancy has not been established. It is not known whether acipimox is secreted in human milk. Like most drugs, OLBETAM should normally be avoided during pregnancy and lactation.

Adverse Effects

The drug may induce skin vasodilation giving rise to a sensation of heat, flushing or itching, especially at the beginning of therapy and also rash and erythema. These reactions usually disappear rapidly during the first days of treatment. Moderate gastric disturbances (heartburn, epigastric pain, nausea and diarrhoea) have also been reported as well as occasionally headache and malaise. On rare occasion patients have developed urticaria, angioedema and bronchospasm; anaphylactoid reactions have also been reported.

Musculoskeletal events including myositis, myalgia, weakness and arthralgia have been reported in patients treated with acipimox.

Interactions

Acipimox is structurally related to nicotinic acid. The risk of the myopathy associated with nicotinic acid is increased when nicotinic acid is administered concomitantly with a statin (i.e. a 3-hydroxy-3-methylglutaryl coenzyme A [HMG-CoA] reductase inhibitor).

No interaction has been shown with digoxin, warfarin and cholestyramine.

Overdosage

If toxic effects are observed, supportive care and symptomatic treatment should be administered.

Pharmaceutical Precautions

Shelf-life: 48 months, store below 30° C.

Medicine Classification

Prescription-only Medicine.

Package Quantities

Packs of 30 capsules.

Further Information

Excipients: Modified corn starch, Silicon dioxide, Magnesium stearate, Sodium lauryl sulphate.

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Date of Preparation

25 May 2005
(Ref: CDS 02/2003)