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.

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

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.

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.

The effect of acipimox on ability to drive or use machinery has not been studied, but based on its pharmacodynamic properties and overall safety profile it is unlikely to have an effect.

**Adverse Effects**

Immune system disorders: Anaphylactoid reactions

Nervous system disorders: Headache

Vascular disorders: Flushing, Vasodilatation

Respiratory, thoracic and mediastinal disorders: Bronchospasm

Gastrointestinal disorders: Dyspepsia, Abdominal pain upper, Nausea, Diarrhea

Skin and subcutaneous tissue disorders: Pruritus, Rash, Erythema, Urticaria, Angioedema

Musculoskeletal and connective tissue disorders: Myositis, Myalgia, Arthralgia

General disorders and administration site conditions: Feeling hot, Malaise, Asthenia.
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.

**Interactions**

The risk of the myopathy is increased when nicotinic acid is administered concomitantly with a statin. As acipimox is structurally related to nicotinic acid caution is recommended when administering both drugs together.

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

**Overdosage**

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

**Contact the National Poisons Centre on 0800 764 766 for advice on the management of an overdose.**

**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.

**Name and Address**

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8 January 2014