SCHEDULING STATUS:
S3

PROPRIETARY NAME(and dosage form):
OLBETAM® (Capsules)

COMPOSITION:
Each capsule contains acipimox 250 mg.

PHARMACOLOGICAL CLASSIFICATION:
A 7.5 Serum-cholesterol reducers.

PHARMACOLOGICAL ACTION:
Acipimox inhibits the release of fatty acids from adipose tissue and reduces the blood concentration of very low density lipoproteins (VLDL or pre-beta) and low density lipoproteins (LDL or beta) with a subsequent overall reduction in triglyceride and cholesterol levels.

Acipimox is rapidly and completely absorbed orally, reaching peak plasma levels within two hours. The half-life is about two hours. It is not significantly metabolized except in the elderly and is eliminated almost completely intact by the urinary route.

INDICATIONS:
OLBETAM is indicated as adjunctive therapy to diet and weight loss in the treatment of type IIa, IIb and IV lipid disorders.

CONTRA-INDICATIONS:
Hypersensitivity to the drug. Peptic ulcer. Pregnancy and while breastfeeding. Patients with renal failure.

WARNING:
Low-cholesterol and low-fat diets are the preferable therapeutic approach before starting treatment with acipimox.
During prolonged treatment periodical checks should be made of blood lipids and lipoproteins and hepatic and renal function.

Clinical trials have excluded patients with heart failure, hepatic and renal impairment, gastric or duodenal ulceration.

DOSAGE AND DIRECTIONS OF USE:
Daily dosage should be adjusted individually depending on plasma triglyceride and cholesterol levels. The dosage most frequently used is between 500-750 mg/day. In particular the lower dose is advised in type IV and the higher dose in types IIa and IIb hyperlipoproteinaemias. Daily dose should be divided and taken with main meals.

Improvements in plasma lipid picture is usually seen within the first month of therapy.

In the elderly it is advisable to reduce the dosage.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Skin vasodilation with a sensation of heat, flushing or itching, especially at the beginning of therapy, rash and erythema. Gastric disturbances including heartburn, epigastric pain, nausea, diarrhoea, headache, asthenia, urticaria, angioedema, bronchospasm and anaphylactic reactions have been reported.

The absorption of OLBETAM is not affected by the concomitant administration of cholestyramine.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
As under "SIDE-EFFECTS".
Treatment: Withdraw the medicine. Treatment is symptomatic and supportive.

IDENTIFICATION:
Opaque hard gelatine capsule with a red cap and red brown body, containing a white to cream powder.

PRESENTATION:
Blister-packed capsules in cartons containing 90 capsules.

STORAGE INSTRUCTIONS:
Store below 25 °C and protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
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NAME AND BUSINESS ADDRESS OF THE APPLICANT:
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