NEW ZEALAND DATA SHEET

1. PRODUCT NAME

OLBETAM 250 mg capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains acipimox 250mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule

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

4. CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Dose and method of administration

Dose

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.

4.3 Contraindications

- Confirmed individual hypersensitivity to OLBETAM

- Peptic ulcer
- Severe Renal Impairment.

4.4 Special warnings and precautions for use

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.

4.5 Interaction with other medicines and other forms of interaction

The risk of the myopathy is increased when nicotininc 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.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safe use in human pregnancy has not been established. Like most drugs, OLBETAM should normally be avoided during pregnancy and lactation.

Lactation

It is not known whether acipimox is secreted in human milk.

Fertility

No data available.

4.7 Effects on ability to drive and use machinery

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.

4.8 Undesirable 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

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

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICUALRS

6.1 List of excipients

Colloidal hydra silica
Modified corn starch,
Silicon dioxide,
Magnesium stearate,
Sodium lauryl sulphate
Iron oxide red
Iron oxide yellow
Titanium dioxide

6.2 Incompatibilities

No data available.

6.3 Shelf life

48 months.

6.4 Special precautions for storage

Store at or below 30° C

6.5 Nature and contents of container

Packs of 30 capsules

Packs of 100 capsules

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription only Medicine

8. SPONSOR

Pfizer New Zealand Limited
P O Box 3998
Auckland, New Zealand

Toll Free Number: 0800 736 363

9. DATE OF FIRST APPROVAL

19 June 1986

10. DATE OF REVISION OF THE TEXT

3rd May 2019

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Reformat to MedSafe Data Sheet as per SmPC format