

Class review on the risk-benefit evaluation of fibrates
Recommendations agreed by the PhVWP at its February 2008 meeting

Section 4.1 Therapeutic indications

For bezafibrate, fenofibrate and ciprofibrate:

[Product name] is indicated as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the following:

- *Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol.*
- *Mixed hyperlipidaemia when a statin is contraindicated or not tolerated.*

For gemfibrozil:

[Product name] is indicated as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the following:

- *Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol.*
- *Mixed hyperlipidaemia when a statin is contraindicated or not tolerated.*
- *Primary hypercholesterolaemia when a statin is contraindicated or not tolerated.*

Section 5.1 Pharmacodynamic properties

The following statement should be included in section 5.1 of the SPC of all fibrates:

There is evidence that treatment with fibrates may reduce coronary heart disease events but they have not been shown to decrease all cause mortality in the primary or secondary prevention of cardiovascular disease.