

### **Annex III**

**Amendments to relevant sections of the summary of product characteristics  
and package leaflets**

## Summary of Product Characteristics

### Section 4.1 – Therapeutic indications

This section should be amended to reflect the wording below

*[Product name] is indicated as alternative or adjunct treatment to reduce triglyceride levels in patients who have not responded adequately to other treatments such as statin or fibrate treatment for:*

- *hypertriglyceridaemia (Fredrickson type IV hyperlipoproteinaemia);*
- *hypercholesterolaemia and hypertriglyceridaemia (Fredrickson type IIb hyperlipoproteinaemia).*

*[Product name] should be used after other measures have been taken such as dietary changes and other non-pharmacological treatment (e.g. exercise, weight reduction).*

*It has not been shown that treatment of hyperlipoproteinaemia with acipimox leads to a reduction of cardiac morbidity or mortality.*

### Section 4.4 – Special warnings and precautions

The wording below should be inserted in this section

*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 one study, Chinese patients taking nicotinic acid plus laropirant concomitantly with simvastatin were reported to have a higher incidence of myopathy and rhabdomyolysis compared to Caucasians.*

## Package leaflet

### 1. What *[Product name]* capsules are and what they are used for

The existing product information shall be amended (insertion, replacement or deletion of the text as appropriate) to reflect the wording below

*This medicine contains acipimox, which is used to treat lipid disorders by reducing high blood levels of certain types of fats called triglycerides. [Product name] capsules should only be used in patients where diet alone or other non-drug measures (weight loss or exercises) failed to correct the levels of these fats.*

*[Product name] capsules should be used in addition to other medicines, such as medicines called 'statins' or 'fibrates' or instead of these medicines where they may not be appropriate or of expected benefit.*

*[Product name] capsules prevent the release of fatty acids from fatty tissue and decrease the blood level of triglycerides and cholesterol.*

### 2. Warnings and precautions

The existing product information shall be amended (insertion, replacement or deletion of the text as appropriate) to reflect the wording below

- *This medicine is not effective for all lipid disorders.*
- *This medicine is not given to prevent heart disease.*
- *Tell your doctor immediately if you have unexplained muscle pain, muscle tenderness or muscle weakness while you are taking this medicine*