

Annex III

Relevant Sections of the Summary of Product Characteristics, Package Leaflet and labelling

**Note: These amendments to the SPC, Package Leaflet and Labelling
are valid at the time of the Commission Decision.**

Amendments to be included in the relevant sections of the Summary of Products Characteristics, Package Leaflet and labelling

Applicable to all products except those containing a polymethacrylate-triethylcitrate coating as modified-release mechanism.

For products having warnings regarding the interaction with alcohol, the existing wording in the SPC and package leaflet should be replaced by the wording below.

For products not having warnings regarding the interaction with alcohol in the currently approved SPC and package leaflet, the below wording should be added.

Summary of Product Characteristics

4.4 Special warnings and precautions for use

[...]

Concomitant use of alcohol and {product name} may increase the undesirable effects of {product name}; concomitant use should be avoided.

[...]

4.5 Interaction with other medicinal products and other forms of interaction

[...]

Alcohol may enhance the pharmacodynamic effects of {product name}; concomitant use should be avoided.

[...]

Package Leaflet

Section 2 – Before you take {product name}

[...]

Drinking alcohol whilst taking {product name} may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you're taking {product name}.

[...]

Labelling

Any existing warnings on the interaction with alcohol should be deleted.