

Annex III

Relevant Sections of the

Summary of Product Characteristics and Package Leaflet

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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

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}.

For oxycodone containing products, the above text should replace the one existing in the respective sections of the Product Information and also the text from the Oxycodone Labelling should be removed.