

Annex III

Amendments to be included in the relevant sections of the summary of product characteristic and package leaflet

Summary of product characteristic

The valid summary of product characteristics is the final version achieved during the Coordination group procedure with the following amendments:

Section 4.1: Therapeutic indications

[The wording of this section should be read as below]

Treatment of postmenopausal osteoporosis. Alendronic acid reduces the risk of vertebral and hip fractures.

Section 5.1: Pharmacodynamic properties

[This section should be amended to reflect the following wording]

[...]

Combination of alendronic acid and alfacalcidol (Valebo):

[...]

[The following wording should be deleted]

“whilst alfacalcidol significantly reduces the frequency of falls in the elderly”

[The following wording should be added]

In some clinical studies, alfacalcidol has been shown to reduce the risk of falls in the elderly.

[...]

Package leaflet

The valid package leaflet is the final version achieved during the Coordination group procedure with the following amendments:

1. WHAT VALEBO IS AND WHAT IT IS USED FOR

[...]

What is alfacalcidol?

[This section should be amended to reflect the following wording]

[...]

In some clinical studies, alfacalcidol has been shown to reduce the risk of falls in the elderly.

[...]