

Stablon (tianeptine)

Recommendations:

- **Amendments to the Product Information**

During the assessment of the information in the PSUR, it has been agreed that the following amendments to the Product Information are required:

- Section 4.4 Special warnings and precautions for use
to include a general warning regarding intake of alcohol as with any psychotropic drug
- Section 4.5 Interactions with other medicinal products and other forms of interactions
to remove interactions with mianserine and alcohol
to replace the undesirable combination ‘non selective MAOI’ with ‘irreversible MAO inhibitors (irponiazide)’
- Section 4.8 Undesirable effects
to update the frequency of drug abuse and dependence (rare to uncommon)