



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Section 4.7: Effects on the ability to drive and use machines

SmPC training presentation

Note: for full information refer to the European Commission's [Guideline on summary of product characteristics \(SmPC\)](#)

SmPC Advisory Group

An agency of the European Union





Index

I. [General objectives](#)

II. [Key principles](#)



I. General objectives of section 4.7

This section should provide information regarding the influence of the medicinal product on the ability to drive and use machine based on:

- The pharmacodynamic and pharmacokinetic profile
- Reported adverse reactions or specific studies in a relevant target population addressing the performance related to driving and road safety or using machines



II. Key principles

Specify whether the medicinal product has:

a) No or negligible influence on these abilities

SmPC examples
1 no influence

b) Minor influence

2 minor influence

c) Moderate influence + special warnings/precautions for use

3 moderate influence

d) Major influence + special warnings/precautions for use + also mention in section 4.4

4 major influence
5 major influence
6 major influence

Other important factors that affect the ability to drive and use machines should be considered if known, e.g. **duration of the impairing effect** and the development of tolerance or adverse reactions with continued use

7 other factors



Example 1-no influence

a) No or negligible influence

Active substance X 1000 IU/0.5 ml solution for injection in a pre-filled syringe

Active substance X has no influence on the ability to drive and use machines.



Example 2–minor influence

b) Minor influence

Active substance X 200 mg solution for injection

Active substance X may have a minor influence on the ability to drive and use machines. Dizziness (including vertigo, vision disorder and fatigue) may occur following administration of active substance X (see section 4.8)



Example 3–moderate influence

c) Moderate influence + special warnings/precautions for use

Active substance X 2 mg prolonged-release tablets

Active substance X has moderate influence on the ability to drive and use machines.

Active substance X may cause drowsiness, therefore the product should be used with caution if the effects of drowsiness are likely to be associated with a risk to safety.



Example 4–major influence

d) Major influence + special warnings/precautions for use + also mention in Section 4.4

Active substance X 0.088 mg tablets

Section 4.7

Active substance X can have a major influence on the ability to drive and use machines.

Hallucinations or somnolence can occur.

Patients being treated with active substance X and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities where impaired alertness may put themselves or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved (see also sections 4.4, 4.5 and 4.8).

Section 4.4

Sudden onset of sleep and somnolence

Active substance X has been associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Sudden onset of sleep during daily activities, in some cases without awareness or warning signs, has been reported uncommonly. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with active substance X. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Furthermore a reduction of the dose or termination of therapy may be considered. Because of possible additive effects, caution should be advised when patients are taking other sedating medicinal products or alcohol in combination with active substance X (see sections 4.5, 4.7 and section 4.8).



Example 5–major influence

d) Major influence + special warnings/precautions for use + also mention in Section 4.4

Active substance XYZ 50 mg/12.5 mg/200 mg film-coated tablets

Section 4.7

Active substance XYZ may have major influence on the ability to drive and use machines. Active substance XYZ together may cause dizziness and symptomatic orthostatism. Therefore, caution should be exercised when driving or using machines. Patients being treated with active substance XYZ and presenting with somnolence and/or sudden sleep onset episodes must be instructed to refrain from driving or engaging in activities where impaired alertness may put themselves or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes have resolved (see section 4.4).

Section 4.4

Active substance Z in association with X has been associated with somnolence and episodes of sudden sleep onset in patients with Parkinson's disease and caution should therefore be exercised when driving or operating machines (see section 4.7).



Example 6–major influence

d) Major influence + special warnings/precautions for use + also mention in Section 4.4

Active substance X 5 mg hard capsules

Section 4.7

Active substance X has major influence on the ability to drive and use machines. Sedation, amnesia, impaired concentration and impaired muscular function may adversely affect the ability to drive or to use machines. If insufficient sleep duration occurs, the likelihood of impaired alertness may be increased (see section 4.5). Caution is recommended for patients performing skilled tasks.

Section 4.4

Complex behaviours such as “sleep-driving” (i.e., driving while not fully awake after ingestion of a sedative-hypnotic, with amnesia for the event) have been reported in patients taking sedative hypnotics. These events can occur in sedative-hypnotic-naïve as well as in sedative-hypnotic experienced persons. Although behaviours such as sleep-driving may occur with a sedative-hypnotic alone at therapeutic doses, the use of alcohol and other central nervous system (CNS) depressants with sedative-hypnotics appears to increase the risk of such behaviours, as does exceeding the maximum recommended dose.



Example 7–other factors

Other **important factors** that **affect the ability to drive and use machines** should be considered if known, e.g. duration of the impairing effect and the development of tolerance or adverse reactions with continued use

Active substance X 0.5 mg/0.5 ml solution for injection

Active substance X has minor or moderate influence on the ability to drive and use machines. Administration of active substance X can cause hypotension and may result in dizziness, light-headedness and blurred vision. Patients should not drive or operate machines for at least 1 hour after receiving active substance X.



Thank you for consulting this training presentation

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Please note the presentation includes examples that may have been modified to best illustrate the related principle