

Tramadol and convulsion, serotonin syndrome, suicide, dosing in the elderly and dosing in patients with renal or hepatic impairment

Final SmPC and PL wording agreed by PhVWP in July 2012

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SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.2

“The dose should be adjusted to the intensity of the pain and the sensitivity of the individual patient. The lowest effective dose for analgesia should generally be selected.” [...]

“Geriatric patients

A dose adjustment is not usually necessary in patients up to 75 years without clinically manifest hepatic or renal insufficiency. In elderly patients over 75 years elimination may be prolonged. Therefore, if necessary the dosage interval is to be extended according to the patient's requirements. “

“Renal insufficiency/dialysis and hepatic impairment

In patients with renal and/or hepatic insufficiency the elimination of tramadol is delayed. In these patients prolongation of the dosage intervals should be carefully considered according to the patient's requirements.

Section 4.5

“Tramadol can induce convulsions and increase the potential for selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, antipsychotics and other seizure threshold-lowering medicinal products (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions.”

“Concomitant therapeutic use of tramadol and serotonergic drugs, such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors (see section 4.3), tricyclic antidepressants and mirtazapine may cause serotonin toxicity. Serotonin syndrome is likely when one of the following is observed:

- *Spontaneous clonus*
- *Inducible or ocular clonus with agitation or diaphoresis*
- *Tremor and hyperreflexia*
- *Hypertonia and body temperature > 38 °C and inducible or ocular clonus.*

Withdrawal of the serotonergic drugs usually brings about a rapid improvement. Treatment depends on the type and severity of the symptoms.”

PACKAGE LEAFLET

How to take <TRADENAME>

“The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken.” [...]

“Elderly patients

In elderly patients (above 75 years) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.”

“Severe liver or kidney disease (insufficiency)/dialysis patients

Patients with severe liver and/or kidney insufficiency should not take <TRADENAME>. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.”

Taking other medicines

“The risk of side effects increases,

- *if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take <TRADENAME> at the same time. Your doctor will tell you whether <TRADENAME> is suitable for you.*

- *if you are taking certain antidepressants. <TRADENAME> may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C.”*