Javna agencija Republike Slovenije
za zdravila in medicinske pripomočke
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VSEM IMETNIKOM DOVOLJENJ ZA PROMET Z ZDRAVILI, KI VSEBUJEJO TRAMADOL

Predložitev spremembe tipa IB – dopolnitev povzetka glavnih značilnosti zdravila in navodila za uporabo za zdravila, ki vsebujejo tramadol

Spoštovani,

Delovna skupina za farmakovigilanco (PhVWP) pri Evropski agenciji za zdravila EMA je v juliju 2012 pregledala podatke, povezane z uporabo tramadola pri starejših bolnikih, pri bolnikih z ledvično in jetrno okvaro ter o uporabi tramadola v povezavi s tveganjem za pojav krčev, serotoninskega sindroma in samomorilnosti. Zaključila je, da je treba informacije v povzetku glavnih značilnosti zdravila in navodilih za uporabo zdravil iz te skupine ustrezno dopolniti.

Imetnike dovoljenj za promet z zadevnimi zdravili, ki vloge za spremembo dovoljenja za promet še niso vložili, prosimo, da Javni agenciji RS za zdravila in medicinske pripomočke v skladu s Pravilnikom o dovoljenju za promet z zdravilom za uporabo v humani medicini (Uradni list RS, št. 109/2010) predložijo **spremembo tipa IB**. Vlogo za zadevna zdravila, ki so pridobila dovoljenje za promet po nacionalnem postopku, imetniki dovoljenj za promet predložijo najkasneje **do 1. oktobra 2012.** Za zdravila, ki so pridobila dovoljenje za promet po mednarodnih postopkih, pa v skladu s časovnico referenčne države članice (RMS). Dodatne informacije in podporna dokumentacija v vlogi niso potrebne.
Zdravila, izdelana po 1. februarju 2013, morajo biti opremljena z novim navodilom za uporabo.

V nadaljevanju vam podajamo odobreno originalno besedilo spremembe, objavljeno je tudi na spletni strani Vodij agencij za zdravila http://www.hma.eu/222.html.

S spoštovanjem,

Pripravila:
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dr. Stanislav Primožič, mag. farm.
namestnik direktorja

po pooblastilu
dr. Matej Breznik, mag. farm.
direktor

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."