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Vsem imetnikom dovoljenj za promet z zdravili, ki vsebujejo selektivne zaviralce privzema serotonina, venlafaksin in mirtazapin

ZAHTEVA ZA PREDLOŽITEV SPREMEMBE TIPA IB – dopolnitev povzetka glavnih značilnosti zdravila in navodila za uporabo za zdravila, ki vsebujejo selektivne zaviralce privzema serotonina (SSRI), venlafaksin in mirtazapin

Spoštovani,

V marcu 2010 je delovna skupina za farmakovigilanco (PhVWP) pri Evropski agenciji za zdravila zaključila oceno podatkov glede tveganja za nastanek persistentne pljučne hipertenzije pri novorojenčkih, ki so bili v nosečnosti izpostavljeni selektivnim zaviralcem privzema serotonina, venlafaksinu ali mirtazapinu. Ocenila je, da podatki kažejo na možno povezavo med zgoraj navedenimi zdravili in nastankom persistentne pljučne hipertenzije pri novorojenčkih, zato je treba povzetke glavnih značilnosti zdravil in navodil za uporabo dopolniti z informacijami glede tega tveganja.

Imetnike dovoljenj za promet z zadevnimi zdravili 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. 59/2006) in obvestilom JAZMP glede nove Uredbe Komisije (ES) št. 1234/2008 z dne 24. 11. 2008 o pregledu sprememb pogojev dovoljenj za promet z zdravili za uporabo v humani medicini in zdravili za uporabo v veterinarski medicini predložijo spremembo tipa IB najkasneje do 1. Junija 2010. Dodatne informacije in podporna dokumentacija v vlogi niso potrebne.

Glede na to, da sta za skupino SSRI predlagani dve spremembi, za fluoksetin pa še dodatna, lahko te spremembe oddate skupaj (posamezne spremembe v tekstu ustrezno označite). Pri tem pa prosimo, da upoštevate, da je treba za vsako spremembo izpolniti obrazec in izvesti ustrezno plačilo.

Odobreno originalno besedilo spremembe je podano v nadaljevanju. Objavljeno je tudi na spletni strani http://www.hma.eu/222.html.

S spoštovanjem,

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SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.6 for all SSRIs
Epidemiological data have suggested that the use of SSRIs in pregnancy, particular in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). The observed risk was approximately 5 cases per 1000 pregnancies. In the general population 1 to 2 cases of PPHN per 1000 pregnancies occur.

Section 4.6 for venlafaxine
Epidemiological data have suggested that the use of SSRIs in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). Although no studies have investigated an association of PPHN to SNRI treatment, this potential risk cannot be ruled out with <TRADENAME/SUBSTANCE> taking into account the related mechanism of action (inhibition of the re-uptake of serotonin).

Section 4.6 for mirtazapine
Epidemiological data have suggested that the use of SSRIs in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). Although no studies have investigated the association of PPHN to mirtazapine treatment, this potential risk cannot be ruled out taking into account the related mechanism of action (increase in serotonin concentrations).

PACKAGE LEAFLET

Section 2 for all SSRIs – subsection pregnancy and breast-feeding
Make sure your midwife and/or doctor know you are on <TRADENAME>.When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like <TRADENAME> may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Section 2 for venlafaxine and mirtazapine – subsection pregnancy and breast-feeding
Make sure your midwife and/or doctor knows you are on <TRADENAME>. When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.