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Javna agencija Republike Slovenije
za zdravila in medicinske pripomočke
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**Vsem imetnikom dovoljenj za promet z
antipsihotiki**

ZAHTEVA ZA PREDLOŽITEV SPREMEMBE TIPA IB – dopolnitev povzetka glavnih značilnosti zdravila (SmPC) in navodila za uporabo (PIL) za antipsihotike glede tveganja za vensko trombembolijo (VTE)

Spoštovani,

Delovna skupina za farmakovigilanco (PhVWP) in Skupina za usklajevanje (CMH(h)) pri Evropski agenciji za zdravila sta ocenili razpoložljive podatke glede tveganja za nastanek venske trombembolije (VTE), povezane z jemanjem antipsihotikov. Podatki kažejo, da povezava med VTE in antipsihotiki ni izključena, zato je sprejeto priporočilo o dopolnitvi povzetkov glavnih značilnosti zdravil in navodil za uporabo antipsihotikov, ki vsebujejo učinkovine, navedene v Dodatku I (List of active substances), z ustreznim opozorilom glede tveganja za VTE.

Imetnike dovoljenj za promet z zadevnimi zdravili, ki še niso predložili vloge, 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 v 30 dneh po objavi obvestila. Dodatne informacije in podporna dokumentacija v vlogi niso potrebne.

Odobreno originalno besedilo spremembe in Dodatek I sta podana v nadaljevanju. Besedilo je objavljeno je tudi na spletni strani <http://www.hma.eu/222.html>.

S spoštovanjem,

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Dodatek I: List of active substances:

Older 'typical' antipsychotics including: acepromazine, benperidol, bromoperidol, buspirone, chlorpromazine, chlorprothixene, clotiapine, cyamemazine, dixyrazine, droperidol, flupenthixol, fluphenazine, fluspirilene, haloperidol, levomepromazine, loxapine, penfluridole, pericyazine, perphenazine, pimozide, pipamerone, pipothiazine, prochlorperazine, promazine, prothipendyl, sulpiride, trifluoperazine and zuclopenthixol, chlorprothixene

Newer 'atypical' antipsychotics: amisulpiride, aripiprazole, clozapine, melperone, olanzapine, paliperidone, quetiapine, risperidone, sertindole, tiapride, ziprasidone and zotepine.

SUMMARY OF PRODUCT CHARACTERISTICS***Section 4.4 - Special warnings and precautions for use***

Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with {Invented name} and preventive measures undertaken.

Section 4.8 Undesirable effects***If no cases with specific product***

Cases of venous thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs- Frequency unknown

If cases with specific product

Venous thromboembolism should be listed as appropriate

PACKAGE LEAFLET***Section 2 - Take special care with {Invented name}:***

If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots

Section 4 - Possible side effects

Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.