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Javna agencija Republike Slovenije
za zdravila in medicinske pripomočke

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Vsem imetnikom dovoljenj za promet z zdravili, ki vsebujejo hidroklortiazid

ZAHTEVA ZA PREDLOŽITEV SPREMEMBE TIPA II – dopolnitev povzetka glavnih značilnosti zdravila (SmPC) in navodila za uporabo (PIL) za zdravila, ki vsebujejo hidroklortiazid, v povezavi z uporabo v nosečnosti

Spoštovani,

Delovna skupina za farmakovigilanco (PhVWP) je na podlagi ocene podatkov glede tveganja pri uporabi hidroklortiazida v nosečnosti marca 2009 izdala priporočilo za dopolnitev povzetka glavnih značilnosti zdravil in navodil za uporabo zadevnih zdravil z novimi informacijami.

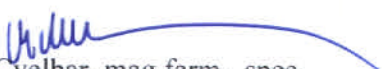
Imetnike dovoljenj za promet z zadevnimi zdravili prosimo, da Javni agenciji RS za zdravila in medicinske pripomočke v skladu s Pravilnikom o dovoljenju za promet z zdravilom za uporabo v humani medicini (Uradni list RS, št. 59/2006) predložijo spremembo tipa II najkasneje v 30 dneh po prejemu obvestila. Dodatne informacije in podporna dokumentacija v vlogi niso potrebne. Ta dopis je objavljen na spletni strani JAZMP www.jazmp.si.

V nadaljevanju vam podajamo odobreno originalno besedilo spremembe.

Besedilo je objavljeno tudi na spletni strani Vodij agencij za zdravila <http://www.hma.eu>.

S spoštovanjem,




dr. Martina Cvelbar, mag.farm., spec.
Direktorica

SPC

Section 4.6

"There is limited experience with hydrochlorothiazide during pregnancy, especially during the first trimester. Animal studies are insufficient.

Hydrochlorothiazide crosses the placenta. Based on the pharmacological mechanism

of action of hydrochlorothiazide its use during the second and third trimester may compromise foeto-placental perfusion and may cause foetal and neonatal effects like icterus, disturbance of electrolyte balance and thrombocytopenia.

Hydrochlorothiazide should not be used for gestational oedema, gestational hypertension or preeclampsia due to the risk of decreased plasma volume and placental hypoperfusion, without a beneficial effect on the course of the disease.

Hydrochlorothiazide should not be used for essential hypertension in pregnant women except in rare situations where no other treatment could be used.

Package Leaflet

Pregnancy and breastfeeding

You must tell your doctor if you are pregnant or if you think that you are. Usually, your doctor will advise you to take another medicine instead of [product], as [product] is not recommended during pregnancy. This is because [product] crosses the placenta and its use after the third month of pregnancy may cause potentially harmful foetal and neonatal effects.