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Vsem imetnikom dovoljenj za promet z zdravili iz skupine antagonisti angiotenzina II

ZAHTEVA ZA PREDLOŽITEV SPREMEMBE TIPA II – dopolnitev povzetka glavnih značilnosti zdravila (SmPC) in navodila za uporabo (PIL) za celotno skupino antagonistov angiotenzina II glede uporabe med dojenjem

Spoštovani,

Javna agencija RS za zdravila in medicinske pripomočke (JAZMP), v skladu s priporočilom Delovne skupine za farmakovigilanco (PhVWP) ter Koordinacijske skupine za zdravila za uporabo v humani medicini (CMD(h)) pri Evropski agenciji za zdravila (EMEA),

poziva vse imetnike dovoljenj za promet z antagonisti angiotenzina II k predložitvi spremembe tipa II za zadevna zdravila.

Delovna skupina za farmakovigilanco (PhVWP) je na osnovi ocene podatkov o uporabi antagonistov angiotenzina II med dojenjem zaključila, da je treba povzetke glavnih značilnosti zdravila in navodila za uporabo teh zdravil posodobiti v skladu z Dodatkoma I in II.
Pri že objavljenem besedilu za antagoniste angiotenzina II o nosečnosti (JAZMP, februar 2008) je prišlo do kasnejše spremembe besedila navodil za uporabo (PIL). Prosimo, da pri oddaji vloge za spremebmo tipa II za dojenje vključite tudi spremembno za nosečnost.

Imetniki dovoljenj za promet z zadevnimi zdravili morajo 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) predložiti spremembo tipa II čim prej, oz. 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 končno odobreno originalno besedilo spremembe.

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

S spoštovanjem,

JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA ZDRAVILA IN MEDICINSKE PRIPOMOČKE
REPUBLIKA SLOVENIJA

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

Annex I
Summary of Product Characteristics

Section 4.3 Contraindication
Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
[Contraindication for lactation to be deleted, if applicable]

Section 4.4 Special warnings and precautions for use
Pregnancy: AIIRAs should not be initiated during pregnancy. Unless continued AIIRA therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with AIIRAs should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Section 4.6 Pregnancy and lactation
Pregnancy:

The use of AIIRAs is not recommended during the first trimester of pregnancy (see section 4.4). The use of AIIRAs is contraindicated during the second and third trimesters of pregnancy (see sections 4.3 and 4.4).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with Angiotensin II Receptor Inhibitors (AIIRAs), similar risks may exist for this class of drugs. Unless continued AIIRA therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with AIIRAs should be stopped immediately and, if appropriate, alternative therapy should be started.

Exposure to AIIRA therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3.)
Should exposure to AIIRAs have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.
Infants whose mothers have taken AIIRAs should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation:
Because no information is available regarding the use of [Product] during breastfeeding, [Product] is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

Annex II:
Package Leaftlet

Before you take [Product]

Do not take [Product]
If you are more than 3 months pregnant. (It is also better to avoid [Product] in early pregnancy – see pregnancy section.)
[Contraindication for lactation to be deleted, if applicable]

Take special care with [Product]
You must tell your doctor if you think you are (or might become) pregnant. [Product] is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Pregnancy and breast feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Product] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Product]. [Product] is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. [Product] is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.