

MEDICAL REVIEW

ADDENDUM

NDA No.: 20-386/SE1-028

DRUG NAME: COZAAP... Tablets (Losartan Potassium)

SPONSOR: Merck & Co., Inc.

West Point, Pennsylvania 19486

TYPE OF DOCUMENT: New Drug Application-Efficacy Supplement

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MEDICAL REVIEWER: Juan Carlos Pelayo, M.D.

ERRATA

1. The statement in page 5:

... Hence, the retrospective nature of the subgroup analysis together with the lack of statistical power for such analysis precludes any valid conclusion on the use of losartan in special populations.
should read:

... Hence, the lack of statistical power for a subgroup analysis precludes any valid conclusion on the use of losartan in special populations.

2. The statement in page 7:

...Subgroup analysis of the primary endpoint by demographic variables or baseline factors is of interest, but its retrospective nature together with the lack of statistical power preclude any valid conclusion on the use of losartan in special populations.
should read:

... Subgroup analysis of the primary endpoint by demographic variables or baseline factors is of interest, but the lack of statistical power precludes any valid conclusion on the use of losartan in special populations.

3. The statement in page 24:

... The retrospective nature of the analysis in addition to the small number of patients in each category per group precludes a valid commentary on the findings.
should read:

... The small number of patients in each category per group, i.e., the lack of statistical power, precludes a valid commentary on the findings..-----

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/s/

Juan Carlos Pelayo

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MEDICAL OFFICER