



Datum: 15.04.2016
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Unser Zeichen: PHV-9016945-A-160414
Ihr Zeichen:

PHV-issue: Amlodipinbesilat, Ramipril

Sehr geehrte Damen und Herren,

Infolge des PSUR Single Assessments (Amlodipinbesilat/ Ramipril) durch den Ausschuss für Risikobewertung im Bereich Pharmakovigilanz (PRAC) kam das CMDh zu dem Schluss europaweit auch die Fach- und Gebrauchsinformation aller Amlodipinbesilat-/ Ramipril-hältigen Monoprodukte zu ändern. (siehe: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2016/01_2016_CMDh_Press_Release.pdf)



Products containing amlodipine besilate as monocomponent:

SmPC Section 4.5

There is a risk of increased tacrolimus blood levels when co administered with amlodipine. In order to avoid toxicity of tacrolimus, administration of amlodipine in a patient treated with tacrolimus requires monitoring of tacrolimus blood levels and dose adjustment of tacrolimus when appropriate.

Clarithromycin is an inhibitor of CYP3A4. There is an increased risk of hypotension in patients receiving clarithromycin with amlodipine. Close observation of patients is recommended when amlodipine is co administered with clarithromycin

SmPC Section 4.8

SOC Nervous system disorders: Extrapyramidal disorder, frequency "Not known".

PL Section 2

Tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ).

Clarithromycin (for infections caused by bacteria).

PL Section 4

Not known: trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

Products containing ramipril as monocomponent:

SmPC Section 4.5

Trimethoprim and in fixed dose combination with sulfamethoxazole (Co-trimoxazole): An increased incidence of hyperkalaemia was observed in patients taking ACE Inhibitors and Trimethoprim and in fixed dose combination with sulfamethoxazole (Co-trimoxazole);

mTOR inhibitors: An increased risk of angioedema is possible in patients taking concomitant medications such as mTOR inhibitors (e.g. Temsirolimus, Everolimus, Sirolimus). Caution should be used when starting therapy.

SmPC Section 4.8

SOC Endocrine disorders: Syndrome of inappropriate antidiuretic hormone secretion (SIADH), frequency "not known".

PL Section 2

Trimethoprim and co-trimoxazole (for infections caused by bacteria)

Temsirolimus (for cancer)

Everolimus (for prevention of graft rejection)

PL Section 4

Not known: concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion. If you have these symptoms contact your doctor as soon as possible.