Bundesamt für Sicherheit
im Gesundheitswesen

BASG / AGES
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Unser Zeichen:	PHV-9016631-A-160414
Ihr Zeichen:	

PHV-issue: Verapamil

Sehr geehrte Damen und Herren,

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

Verapamil extended release tablets

Section 4.5

When oral verapamil was co-administered with dabigatran etexilate (150 mg), a P- gp substrate, the Cmax and AUC of dabigatran were increased but magnitude of this change differs depending on time between administration and the formulation of verapamil. Co- administration of verapamil 240 mg extended-release at the same time as dabigatran etexilate resulted in increased dabigatran exposure (increase of Cmax by about 90 % and AUC by about 70 %).

Close clinical surveillance is recommended when verapamil is combined with dabigatran etexilate and particularly in the occurrence of bleeding, notably in patients having a mild to moderate renal impairment.

Verapamil Immediate release tablets

Section 4.5

When oral verapamil was co-administered with dabigatran etexilate (150 mg), a P- gp substrate, the Cmax and AUC of dabigatran were increased but magnitude of this change differs depending on time between administration and the formulation of verapamil. When verapamil 120 mg immediate -release was co-administered one hour before a single dose of dabigatran etexilate, the dabigatran Cmax was increased by about 180 % and AUC by about 150 %. No meaningful interaction was observed when verapamil was administered 2 hours after dabigatran etexilate (increase of Cmax by about 10% and AUC by about 20%).

Close clinical surveillance is recommended when verapamil is combined with dabigatran etexilate and particularly in the occurrence of bleeding, notably in patients having a mild to moderate renal impairment.

Fixed dose combination of verapamil and quinidine, film-coated, immediate release tablet (Cordichin)

Section 4.5

Quinidine and verapamil both are P-glycoprotein inhibitors and both agents have been reported to increase Cmax and AUC of dabigatran, which is a P-gp substrate. Close clinical surveillance is recommended when the FDC tablet is combined with dabigatran etexilate and particularly in the occurrence of bleeding, notably in patients having a mild to moderate renal impairment.

Fixed dose combination of verapamil and hydrochlorothiazide, modified release tablet (Isoptin RR plus)

Section 4.5

When oral verapamil was co-administered with dabigatran etexilate (150 mg), a P- gp substrate, the Cmax and AUC of dabigatran were increased but magnitude of this change differs depending on time between administration and the formulation of verapamil. Co- administration of verapamil 240 mg extended-release at the same time as dabigatran etexilate resulted in increased dabigatran exposure (increase of Cmax by about 90 % and AUC by about 70 %).

Close clinical surveillance is recommended when verapamil is combined with dabigatran etexilate and particularly in the occurrence of bleeding, notably in patients having a mild to moderate renal impairment.

Fixed dose combination of verapamil, triamterene and hydrochlorothiazide, film-coated, immediate release tablet (Veratide)

Section 4.5

When oral verapamil was co-administered with dabigatran etexilate (150 mg), a P- gp substrate, the Cmax and AUC of dabigatran were increased but magnitude of this change differs depending on time between administration and the formulation of verapamil. When verapamil 120 mg immediate -release was co-administered one hour before a single dose of dabigatran etexilate, the dabigatran Cmax was increased by about 180 % and AUC by about 150 %. No meaningful interaction was observed when verapamil was administered 2 hours after dabigatran etexilate (increase of Cmax by about 10% and AUC by about 20%).

Close clinical surveillance is recommended when verapamil is combined with dabigatran etexilate and particularly in the occurrence of bleeding, notably in patients having a mild to moderate renal impairment.

Other medicines and <Product name>

Other medicines that may react with <Product name>:
dabigatran (medicine to prevent the formation of blood clots)

IV verapamil

No information in the package leaflet about this interaction is considered necessary.