

# Dapoxetine + diverse stoffen: sildenafil/tadalafil/vardenafil

11061a

Onderbouwend	Stof	Effect	Code
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Ontkrachtend	Stof	Effect
Dresser MJ. Int J Impot Res 2006;18:104–10.	dapoxetine + tadalafil	Geen effect van tadalafil op kinetiek dapoxetine. Dapoxetine vs dapoxetine+tadalafil: Cmax 372 vs 370 ml ng/ml AUC 2070 vs 2100 ng.h/ml Regime: dapoxetine 60 mg 1-malig alleen en icm tadalafil 20 mg 1-malig bij 22 vrijwilligers; cross-over study, washout 6-14 dagen The 90% CIs for the mean ratios of Cmax and of AUCinf were within the standard no effect boundary of 80–125% <sup>18,21</sup> for dapoxetine
SPC Priligy	dapoxetine + tadalafil	geen invloed van tadalafil 1-malig 20 mg op kinetiek dapoxetine.

Overig	Stof	Effect
Dresser MJ. Int J Impot Res 2006;18:104–10.	dapoxetine + sildenafil / vardenafil	Dapoxetine vs dapoxetine+sildenafil: Cmax 372 vs 386 ng/ml AUC 2070 vs 2530 ng.h/ml Regime: dapoxetine 60 mg 1-malig alleen en icm sildenafil 100 mg 1-malig bij 22 vrijwilligers; cross-over study, washout 6-14 dagen. The 90% CI of the ratio of dapoxetine + sildenafil to dapoxetine alone for: - In Cmax (natural logarithm of Cmax) within the no-effect boundary of 80–125% - AUCinf outside the no-effect boundary of 80–125% → WFG: toename AUC valt binnen de ruis. Based on the results of this study and what is known about the metabolism of vardenafil and sildenafil, it is reasonable to anticipate that vardenafil would not significantly alter the pharmacokinetics of dapoxetine and that dapoxetine would not alter the pharmacokinetics of vardenafil. As is the case with sildenafil and tadalafil, vardenafil is metabolized predominantly by CYP3A4, and has either no or only weak inhibitory effects on CYP isoforms.
SPC Priligy	dapoxetine + sildenafil	toename AUC dapoxetine met 22% en Cmax met 4% door sildenafil. Naar verwachting niet klinisch relevant. Regime: sildenafil 100 mg 1-malig, dapoxetine 60 mg 1-malig in crossover-studie. → GIC: getallen komen uit Dresser 2006.

## Opmerkingen

Stockley: theoretically, syncope and orthostatic hypotension could be more common if phosphodiesterase type-5-inhibitor is given with dapoxetine.

Hansten / PubMed: geen gegevens

Alfanum. code	sildenafil: --	tadalafil: --	vardenafil: --
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Risicogroep
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	Code	Interactie	Actie	Datum
Beslissing WFG	--	Nee	Nee	24 september 2013

# Dapoxetine + diverse stoffen: midazolam

11061b

Onderbouwend	Stof	Effect	Code
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Overig	Stof	Effect
SPC Priligy	midazolam + dapoxetine	afname AUC midazolam met 20% (variërend van -60 tot +18%). De klinische relevantie is waarschijnlijk gering. Regime: dapoxetine 60 mg/dag gedurende 6 dagen, midazolam 8 mg 1-malig (niet vermeld of dit orale of iv toediening is) Dapoxetine is zwakke CYP2D6-remmer; geen remmer van CYP3A4/2C9/2C19. → WFG: afname AUC valt binnen de ruis.

## Opmerkingen

Stockley: dapoxetine has no clinically relevant effect on the pharmacokinetics of midazolam; nevertheless the manufacturer suggests that a clinically relevant interaction may still occur with other drugs metabolised similarly to midazolam that have a narrow therapeutic window.

PubMed: geen gegevens.

Alfanum. code	--			
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Risicogroep				
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	Code	Interactie	Actie	Datum
Beslissing WFG	--	Nee	Nee	24 september 2013