Pitolisant + Diverse stoffen 13609

itraconazol, tricyclische antidepressiva, mianserine, mirtazapine

Onderbouwend	Stof	Effect	Code
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Overig	Stof	Effect
EPAR Wakix	pitolisant + itraconazol	geen invloed itraconazol op absorptie en blootstelling pitolisant. Kleine afname AUC (11%) en Cmax (27%) metaboliet BP2.951. Regime: itraconazol 200 mg/dag gedurende 7 dagen, pitolisant 20 mg eenmalig, 18 gezonde personen. Based on the results of itraconazole study, the CHMP concluded that clinically relevant interactions following the co-administration of pitolisant with inhibitors of CYP3A4 is unlikely. However, these results were not expected since in vitro data demonstrated the major role of CYP3A4 (and CYP2D6) in the metabolism of pitolisant, in accordance to the significant decrease (about 50%) of pitolisant exposure observed with rifampicin.
SPC Wakix	pitolisant + tri- en tetracyclische antidepressiva	tri- of tetracyclische antidepressiva (bijv. imipramine, clomipramine, mirtazapine) kunnen de werkzaamheid van pitolisant verminderen omdat ze een remmende werking vertonen op de histamine H1-receptor en mogelijk het effect van endogene histamine dat wordt vrijgegeven in de hersenen door de behandeling, teniet doen.
EPAR Wakix	pitolisant + tri- en tetracyclische antidepressiva	concomitant administration of tri or tetracyclic antidepressants (e.g. imipramine, clomipramine, mirtazapine) and anti-histamines (H1-receptor antagonists) crossing the hemato-encephalic barrier (e.g. pheniramine maleate, chlorpheniramine, diphenydramine, promethazine, mepyramine) with pitolisant is not recommended since the endogenous histamine released in brain by these treatments could be altered. No clinical data supporting this assumption were provided. However, this interaction is pharmacologically plausible since pitolisant and these two classes of products target the same histamine brain receptors.

Opmerkingen

Pubmed, Stockley: --

Risicofactoren	
Mitigerende factoren	

	Interactie	Actie	Datum
Beslissing WFG	Nee	Nee	10 oktober 2017