# Omeprazol + Zanubrutinib | M 8571

| Onderbouwend | Stof | Effect | Code |
|---|---|---|---|
| Ou YC.<br>Br J Clin Pharmacol 2021;87:2926-36.<br><br>ratios (%) of geometric least squares means (90% confidence intervals) AUC in the presence/absence of zanubrutinib. | omeprazol<br>+ zanubrutinib | ↓AUC met 36% (451.8→282.2 h*ng/ml), ratio AUC 63.5%; ratio Cmax 79.5%<br>Regime: zanubrutinib 160 mg 2dd op dag 7 t/m 19; omeprazole 20 mg (CYP2C19) single dose on day 5 and day 18; single-sequence study in 18 healthy male volunteers.<br>Conclusions: Z 320 mg/day decreased the systemic exposure of CYP3A and CYP2C19 substrates (mean reduction <50%), and had minimal or no effect on the activity of P-gp, CYP2C9 and BCRP. | 3A |
| SPC + EPAR Brukinsa<br><br>Brukinsa FDA product label. | omeprazol<br>+ zanubrutinib | getallen lijken op die van Ou 2021.<br>↓AUC omeprazol (CYP2C19 substraat) met 36% en Cmax met 20% → GIC: geen details omtrent duur gebruik zanubrutinib, patient of vrijwilliger.<br>p.62 EPAR: zanubrutinib as a perpetrator was investigated in vivo in a cocktail DDI study (BGB-3111-108) with substrates for CYP3A4 (midazolam), CYP2C19 (omeprazole), P-gp (digoxin). | 1A |

| Overig | Stof | Effect |
|---|---|---|
| SPC + EPAR Brukinsa | substraten CYP2C19<br>+ zanubrutinib | voorzichtig bij combinatie met CYP2C19-substraten met kleine therapeutisch breedte |
| EPAR Brukinsa<br><br>PBPK: physiologically-based pharmacokinetic model | Zanubrutinib als dader | p.62 Zanubrutinib as a perpetrator was investigated in vivo in a cocktail DDI study (BGB-3111-108) with substrates for CYP3A4 (midazolam), CYP2C9 (S-warfarin), CYP2C19 (omeprazole), P-gp (digoxin) and BCRP (rosuvastatin, also substrate for OATP1B1, OATP1B3). |
| Wang K.<br>CPT Pharmacometrics Syst Pharmacol 2021;10:441-54.<br>doi: 10.1002/psp4.12605. | substraten +<br>zanubrutinib | PBPK model: model predictions were generally within 1.5-fold of the observed clinical data. The PBPK simulations showed that clinically relevant concentrations of Z as a DDI perpetrator, would have no or limited impact on the enzyme activity of CYP2B6 and CYP2C8. |

**Opmerkingen**
Stockley, PubMed: niets.

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|---|---|
| Risicofactoren | |
| Mitigerende factoren | |

| | Interactie | Actie | Datum |
|---|---|---|---|
| Beslissing WG OncoIA | Ja | Nee | 25-6-25 |