# ロナセンテープ

# 製造販売承認申請

# CTD 第 2 部

## 2.7　臨床概要

## 2.7.5　参考文献

大日本住友製薬株式会社

## 2.7.2 で使用した参考文献


1) 日本腎臓学会編. CQ1-2. CKD の重症度はどのように評価するか. In:エビデンスに基づく CKD 診療ガイドライン 2018. 東京: 東京医学社; 2018. P.2-5. 【5.4.44】
2) Olkkola KT, Backman JT, Neuvonen PJ. Midazolam should be avoided in patients receiving the systemic antimycotics ketoconazole or itraconazole. Clin Pharmacol Ther. 1994 ;55:481-5. 【5.4.45】
3) Katzenmaier S, Markert C, Riedel KD, Burhenne J, Haefeli WE, Mikus G. Determining the Time Course of CYP3A Inhibition by Potent Reversible and Irreversible CYP3A Inhibitors Using A Limited Sampling Strategy. Clin Pharmacol Ther. 2011;90:666-73. 【5.4.46】
4) Niwa T, Imagawa Y, Yamazaki H. Drug Interactions between Nine Antifungal Agents and Drugs Metabolized by Human Cytochromes P450. Curr Drug Metab. 2014;15:651-79. 【5.4.47】
5) de Jonge H, de Loor H, Verbeke K, Vanrenterghem Y, Kuypers DR. In vivo CYP3A activity is significantly lower in cyclosporine-treated as compared with tacrolimus-treated renal allograft recipients. Clin Pharmacol Ther. 2011;90:414-22. 【5.4.48】
6) Friedman EJ, Fraser IP, Wang YH, Bergman AJ, Li CC, Larson PJ et al. Effect of Different Durations and Formulations of Diltiazem on the Single-Dose Pharmacokinetics of Midazolam:How Long Do We Go? J Clin Pharmacol. 2011;51:1561-70. 【5.4.49】
7) Farde L, Wiesel FA, Halldin C, Sedvall G. Central D2-dopamine receptor occupancy in schizophrenic patients treated with antipsychotic drugs. Arch Gen Psychiatry. 1988;45:71-6. 【5.4.50】
8) Kapur S, Zipursky R, Jones C, Remington G, Houle S. Relationship between dopamine D2 occupancy, clinical response, and side effects: a double-blind PET study of first-episode schizophrenia. Am J Psychiatry. 2000;157:514-20. 【5.4.51】
9) Moriguchi S, Bies RR, Remington G, Suzuki T, Mamo DC, Watanabe K. Estimated dopamine $D_2$ receptor occupancy and remission in schizophrenia: analysis of the CATIE data. J Clin Psychopharmacol. 2013;33:682-5. 【5.4.52】
10) Tateno A, Arakawa R, Okumura M, Fukuta H, Honjo K, Ishihara K et al. Striatal and extrastriatal dopamine D2 receptor occupancy by a novel antipsychotic, blonanserin: a PET study with [11C]raclopride and [11C]FLB 457 in schizophrenia. J Clin Psychopharmacol. 2013;33:162-9. 【5.4.53】


## 2.7.3 で使用した参考文献


1) Guidance on the clinical investigation of medicinal products, including depot preparations, in the treatment of schizophrenia. EMA/CHMP/40072/2010 Rev.1 (Sep.20.2012). European Medicines Agency. 【5.4.54】
2) Perkins DO, Stroup TS, Lieberman JA. Psychotic disorders measures. In: Handbook of

Psychiatric Measures. Washington DC: American Psychiatric Association; 2000. p.485-497. 【5.4.55】

3) Williams JBW. Mental health status, functioning, and disabilities measures. In: Handbook of Psychiatric Measures. Washington DC: American Psychiatric Association; 2000. p.93-115. 【5.4.56】
4) 尾鷲登志美、上島国利. VIII 治療評価 1. 治療遵守度と adherence. 臨床精神医学増刊号.2004;599-616. 【5.4.57】
5) Proschan MA, Lan KKG, Wittes JT, Statistical Monitoring of Clinical Trials: A Unified Approach. Springer: NY York,2010. 【5.4.71】
6) Bretz F, Koenig F, Brannath W, Glimm E, Posh M, TUTORIAL IN BIOSTATISTICS Adaptive designs for confirmatory clinical tials. Statistics in Medicine 2009; 28:1181-1217. 【5.4.72】
7) De Las Cuevas C, Peñate W. Explaining pharmacophobia and pharmacophilia in psychiatric patients: relationship with treatment adherence. Hum Psychopharmacol. 2015 Sep;30(5):377-83. 【5.4.60】

## 2.7.4 で使用した参考文献

1) 日本腎臓学会編. CQ1-2. CKD の重症度はどのように評価するか. In:エビデンスに基づく CKD 診療ガイドライン 2018. 東京: 東京医学社; 2018. P.2-5. 【5.4.44】