

CARIPRAZINE'S SAFETY PROFILE OVER THE APPROVED DOSE RANGE

Elmars Rancans¹, Réka Csehi², György Németh²

¹ Riga Stradins University, Department of Psychiatry and Narcology, Riga, Latvia

² Global Medical Division, Gedeon Richter Plc., Budapest, Hungary

OBJECTIVE

To report the **safety profile** of cariprazine **over the approved dose range** (i.e., above 6.0 mg/day) in schizophrenia patients using **real-world** and **clinical trial data**.

CONCLUSIONS

Cariprazine showed a **similar safety profile** above and within the approved dose range

NOTE: Cariprazine is approved in the dose range of 1.5 to 6.0 mg/day. Clinicians are advised to adhere to these doses whenever possible.

Presented at the 23rd WPA World Congress of Psychiatry, 28 September – 1 October, 2023, Vienna

INTRODUCTION

- Cariprazine's favourable safety profile has been demonstrated in both clinical trials and real-life settings, in various indications.
- In schizophrenia, cariprazine's approved dose range is 1.5-6.0 mg/day.
- However, doses above 6 mg/day were tested in clinical trials and are used in real-life settings.

METHODS

- Clinical trials:** Pooled analysis of four short-term (NCT00404573, NCT01104766, NCT01104779, NCT00694707), and three long-term (NCT00839852, NCT01104792, NCT01412060) schizophrenia studies evaluated the safety of cariprazine over 6 mg/day. Descriptive statistics were used.
- Real-world settings:** A literature search was performed to identify articles reporting on the safety of cariprazine above 6 mg/day in schizophrenia patients.

RESULTS

- Clinical trials:** The pooled analysis (cariprazine 9-12 mg/day: n=741; placebo: n=683) revealed that cariprazine in high doses demonstrated similar safety profile as within the approved dose range (**Table 1**).
- Real-world data:** Two single-arm reports^{1,2} were identified (cariprazine up to 7.5mg/day; up to 9mg/day). The side-effects reported in more than 10% of patients included akathisia and anxiety.

Table 1. Incidence of treatment emergent adverse events during treatment period in the cariprazine schizophrenia program*

	Placebo (n=683) n (%)	Cariprazine 1.5–6 mg (n=2048) n (%)	Cariprazine 9-12 mg (n=741) n (%)
Patients with ≥ one AE	467 (68.4)	1569 (76.6)	610 (82.3)
Gastrointestinal disorders			
Nausea	31 (4.5)	141 (6.9)	40 (5.4)
Constipation	32 (4.7)	113 (5.5)	48 (6.5)
Nervous system disorders			
Akathisia	23 (3.4)	299 (14.6)	107 (14.4)
Headache	81 (11.9)	247 (12.1)	94 (12.7)
Extrapyramidal disorder	22 (3.2)	143 (7.0)	58 (7.8)
Psychiatric disorders			
Insomnia	69 (10.1)	287 (14.0)	94 (12.7)
Restlessness	20 (2.9)	126 (6.2)	53 (7.2)
Schizophrenia	60 (8.8)	101 (4.9)	41 (5.5)
Investigations			
Weight increased	10 (1.5)	104 (5.1)	50 (6.7)

*All adverse events are reported that emerged in at least 5% of patients in the high-dose cariprazine group.

References: 1. Rancans et al. Int Clin Psychopharmacol. 2021;36:154–161.; 2. Galmes, L.N. & Rancans, E. Front Psychiatry. 2023;14:1112697.