28 hard capsules 1,5 mg; 3mg; 4,5 mg; 6 mg	
Public price	€ 55,67
Co-payment regular insured patient	€ 12,10
Co-payment preferential insured patient	€ 8,00

NAME OF THE MEDICINAL PRODUCT Reagila 1.5 mg - 3 mg - 4.5 mg - 6 mg, hard capsules **QUALITATIVE AND QUANTITATIVE COMPOSITION** Each hard capsule contains cariprazine hydrochloride corresponding to 1.5 mg – 3 mg – 4.5 mg – 6 mg cariprazine. Excipient with known effect: Reagila 3 mg hard capsules Each hard capsule contains 0.0003 mg Allura red AC (E 129). Reagila 4.5 mg hard capsules Each hard capsule contains 0.0008 mg Allura red AC (E 129). Reagila 6 mg hard capsules Each hard capsule contains 0.0096 mg Allura red AC (E 129). **PHARMACEUTICAL FORM** Hard capsule. The capsules are filled with white to yellowish white powder mixture. **THERAPEUTIC INDICATIONS** Reagila is indicated for the treatment of schizophrenia in adult patients. **POSOLOGY AND METHOD OF ADMINISTRATION** Posology The recommended starting dose of cariprazine is 1.5 mg once daily. Thereafter the dose can be increased slowly in 1.5 mg increments to a maximum dose of 6 mg/day, if needed. The lowest effective dose should be maintained according to the clinical judgement of the treating physician. Because of the long half-life of cariprazine and its active metabolites, changes in dose will not be fully reflected in plasma for several weeks. Patients should be monitored for adverse reactions and treatment response for several weeks after starting cariprazine and after each dose change. *Switching from other antipsychotics to cariprazine* When switching from another antipsychotic to cariprazine gradual cross-titration should be considered, with gradual discontinuation of the previous treatment while cariprazine treatment is initiated. *Switching to another antipsychotic from cariprazine* When switching to another antipsychotic from cariprazine, no gradual cross-titration is needed, the new antipsychotic should be initiated in its lowest dose while cariprazine is discontinued. It should be considered that plasma concentration of cariprazine and its active metabolites will decline by 50% in ~1 week. *Missed dose* If the patient misses a dose, the patient should take the missed dose as soon as possible. However, if it is almost time for the next dose, the missed dose should be skipped and the next dose should be taken according to the regular schedule. It is not recommended to take a double dose to make up for the forgotten dose. Special population *Renal impairment* No dose adjustment is required in patients with mild to moderate renal impairment (Creatinine Clearance (CrCl) ≥ 30 mL/min and < 89 mL/min). Safety and efficacy of cariprazine have not been evaluated in patients with severe renal impairment (CrCl < 30 mL/min). Use of cariprazine is not recommended in patients with severe renal impairment. *Hepatic impairment* No dose adjustment is required in patients with mild to moderate hepatic impairment (Child-Pugh score between 5-9). Safety and efficacy of cariprazine have not been evaluated in patients with severe hepatic impairment (Child-Pugh score between 10 and 15). Use of cariprazine is not recommended in patients with severe hepatic impairment. *Elderly* Available data in elderly patients aged ≥ 65 years treated with cariprazine are not sufficient to determine whether or not they respond differently from younger patients. Dose selection for an elderly patient should be more cautious. *Paediatric population* The safety and efficacy of cariprazine in children and adolescents aged less than 18 years have not been established. No data are available. Method of administration Reagila is for oral use, to be taken once daily at the same time of the day with or without food. Alcohol should be avoided when taking cariprazine. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients. Concomitant administration of strong or moderate CYP3A4 inhibitors. Concomitant administration of strong or moderate CYP3A4 inducers. **UNDESIRABLE EFFECTS** Summary of the safety profile The most frequently reported adverse drug reactions (ADRs) with cariprazine in the dose range (1.5-6 mg) were akathisia (19%) and parkinsonism (17.5%). Most events were mild to moderate in severity. List of adverse reactions ADRs based upon pooled data from cariprazine schizophrenia studies are shown by system organ class and by preferred term. Adverse reactions are ranked by frequency, the most frequent first, using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000) very rare (<1/10,000), not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. ***Adverse drug reactions occurring in patients with schizophrenia.*** **Blood and Lymphatic system disorders:** Uncommon: Anaemia, Eosinophilia. Rare: Neutropenia. **Immune system disorders:** Rare: Hypersensitivity. **Endocrine disorders:** Uncommon: Blood thyroid stimulating hormone decreased. Rare: Hypothyroidism. **Metabolism and nutrition disorders:** Common: Dyslipidaemia, Weight increased, Decreased appetite, Increased appetite. Uncommon: abnormal blood sodium, Diabetes mellitus, Blood glucose increased. **Psychiatric disorders:** Common: Sleep disorders[1], Anxiety. Uncommon: Suicidal behaviour, Delirium, Depression, Libido decreased, Libido increased, Erectile dysfunction. **Nervous system disorders:** Very common: Akathisia[2], Parkinsonism[3]. Common: Sedation, Dizziness, Dystonia[4], Other extrapyramidal diseases and abnormal movement disorders[5]. Uncommon: Tardive dyskinesia, Dyskinesia[6], Dysesthesia, Lethargy. Rare: Seizures/Convulsion, Amnesia, Aphasia. Very rare: Neuroleptic malignant syndrome. **Eye disorders:** Common: Vision blurred. Uncommon: intraocular pressure increased, Accommodation disorder, Visual acuity reduced, Eye irritation. Rare: Cataract,

Photophobia. **Ear and labyrinth disorders:** Uncommon: Vertigo. **Cardiac disorders:** Common: Tachyarrhythmia. Uncommon: Cardiac conduction disorders, Bradyarrhythmia, Electrocardiogram QT prolonged, Electrocardiogram T wave abnormal. **Vascular disorders:** Common: Hypertension. Uncommon: Hypotension. **Respiratory, thoracic and mediastinal disorders:** Common: Vomiting, Nausea, Constipation. Uncommon: Gastrooesophageal reflux disease. Rare: Dysphagia. **Hepatobiliary disorders:** Common: Hepatic enzymes increased. Uncommon: Blood bilirubin increased. Very rare: Toxic hepatitis. **Skin and subcutaneous tissue disorders:** Uncommon: Pruritus, Rash. **Musculoskeletal and connective tissue disorders:** Common: Blood creatine phosphokinase increased. Rare: Rhabdomyolysis. **Renal and urinary disorders:** Uncommon: Dysuria, Pollakisuria. **Pregnancy, puerperium and perinatal conditions:** Very rare: Drug withdrawal syndrome neonatal. **General disorders and administration site conditions:** Common: Fatigue. Uncommon: Thirst. [1]Sleep disorders: Insomnia, Abnormal dreams/nightmare, Circadian rhythm sleep disorder, Dyssomnia, Hypersomnia, Initial insomnia, Middle insomnia, Nightmare, Sleep disorder, Somnambulism, Terminal insomnia. [2]Akathisia: Akathisia, Psychomotor hyperactivity, Restlessness. [3]Parkinsonism: Akinesia, Bradykinesia, Bradyphrenia, Cogwheel rigidity, Extrapyramidal disorder, Gait disturbance, Hypokinesia, Joint stiffness, Tremor, Masked facies, Muscle rigidity, Musculoskeletal stiffness, Nuchal rigidity, Parkinsonism. [4]Dystonia: Blepharospasm, Dystonia, Muscle tightness, Oromandibular dystonia, Torticollis, Trismus. [5]Other extrapyramidal diseases and abnormal movement disorders: Balance disorder, Bruxism, Drooling, Dysarthria, Gait deviation, Glabellar reflex abnormal, Hyporeflexia, Movement disorder, Restless legs syndrome, Salivary hypersecretion, Tongue movement disturbance. [6]Dyskinesia: Choreoathetosis, Dyskinesia, Grimacing, Oculogyric crisis, Protrusion tongue. Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: **Belgium:** Federaal agentschap voor geneesmiddelen en gezondheidsproducten, Afdeling Vigilantie, Galileelaan 5/03, 1210 BRUSSEL. Postbus 97, 1000 BRUSSEL, Madou. Website: www.eenbijwerkingmelden.be, e-mail: adr@fagg.be. **MARKETING AUTHORISATION HOLDER** Gedeon Richter Plc. Gyömrői út 19-21. 1103 Budapest Hungary. **MARKETING AUTHORISATION NUMBERS** Reagila 1.5 mg (28 hard capsules): EU/1/17/1209/003. Reagila 3 mg (28 hard capsules): EU/1/17/1209/013. Reagila 4.5 mg (28 hard capsules): EU/1/17/1209/021. Reagila 1.5 mg (28 hard capsules): EU/1/17/1209/029. **GENERAL CLASSIFICATION FOR SUPPLY** Prescription only. **DATE OF REVISION OF THE TEXT** 04/2022