Citidaron (Cytisinicline) Abbreviated Prescribing Information. Please refer to the Summary of Product Characteristics for full details.

Product name: Citidaron 1.5mg tablets Composition: 1.5mg of Cytisinicline (previously used name: cytisine) **Indication:** Smoking cessation and reduction of nicotine cravings in smokers willing to stop. Treatment goal is the permanent cessation of use of nicotine-containing products. **Posology and administration:** Adults: One pack (100 tablets) is sufficient for a complete treatment course of 25 days: Day 1-3: 1 tablet every 2 hours (maximum 6 per day); Day 4-12: 1 tablet every 2.5 hours (maximum 5 per day); Day 13-16: 1 tablet every 3 hours (maximum 4 per day); Day 17-20: 1 tablet every 5 hours (maximum 3 per day); Day 21-25: 1-2 tablets a day (maximum 2 per day). Stop smoking no later than 5th day of treatment; continuing smoking may aggravate adverse reactions. In case of treatment failure, discontinue; may be resumed after 2 to 3 months. **Special populations:** *Renal or hepatic impairment:* no clinical experience; not recommended. *Elderly (over 65 years):* limited clinical experience; not recommended. *Paediatric population (under 18 years):* Safety and efficacy not established; not recommended. **Method of administration:** Orally with water. **Contraindications:** Hypersensitivity to active substance or excipients; unstable angina; recent myocardial infarction or stroke; clinically significant arrhythmias; pregnancy and breastfeeding. **Warnings and precautions (see SmPC for full details):** Only for patients with serious intention of weaning off nicotine. Patient should be aware that simultaneous smoking or use of nicotine-containing products could lead to aggravated adverse reactions of nicotine. Use with caution in: ischemic heart disease, heart failure, hypertension pheochromocytoma, atherosclerosis and other peripheral vascular diseases, gastric and duodenal ulcer, gastroesophageal reflux disease, hyperthyroidism, diabetes and schizophrenia. Polycyclic aromatic hydrocarbons in tobacco smoke induce metabolism by CYP 1A2 (and possibly CYP 1A1). Stopping smoking may slow metabolism and raise blood levels of such drugs. Potentially clinically important if narrow therapeutic window, e.g. theophylline, tacrine, clozapine, ropinirole. Levels of products partly metabolised CYP1A2 e.g. imipramine, olanzapine, clomipramine, fluvoxamine, may also increase; data are lacking, clinical significance unknown. Limited data indicate metabolism of flecainide and pentazocine may be induced by smoking. Be aware of serious neuropsychiatric symptoms in patients attempting to quit smoking, with or without treatment, including: depressed mood, rarely including suicidal ideation and suicide attempt; exacerbation of underlying psychiatric illness (e.g. depression) - take care in these patients and advise accordingly. (See Pregnancy). **Pregnancy:** Contraindicated. Women of childbearing potential must use highly effective contraception. If on systemically acting hormonal contraceptives, add a second barrier method. **Breastfeeding:** Contraindicated. **Fertility:** No data available. **Undesirable effects: Very Common (≥1/10):** change in appetite (mainly increase), weight gain, dizziness, irritability, mood changes, anxiety, sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headaches, tachycardia, hypertension, dry mouth, diarrhea, nausea, changes flavour, heartburn, constipation, vomiting, abdominal pain (especially in the upper abdomen), rash, myalgia, fatigue **Common (≥1/100 to <1/10):** difficulty in concentration, slow heart rate, abdominal distension, burning tongue, malaise. **Price:** https://www.consilienthealth.ie/our-medicines/pricing-of-our-medicines/ **Legal Classification: POM. MA number: PA22714/001/001. Marketing Authorisation Holder: Aflofarm Farmacja Polska Sp. z o.o. CRN00D3GH, Partyzancka 133/151 Pabianice 95-200 Poland. Further information is available on request from Consilient Health Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14. Job Code: IE-CYT-1(5) Date of preparation: November 2025**

Adverse events should be reported. Reporting forms and information are available from HPRA Pharmacovigilance on the HPRA website www.hpra.ie.

Adverse events should also be reported to Consilient Health at drugsafety@consilienthealth.com or 012057766.