

# TODACITAN<sup>®</sup> CITISINE FOR SMOKING CESSATION

Alternative with a complex dosage regimen



IMPORTANT  
THERAPEUTIC  
INNOVATION



MODEST  
THERAPEUTIC  
INNOVATION



SOME ADDED  
VALUE IN SPECIFIC  
SITUATIONS



**NO THERAPEUTIC  
INNOVATION**



INSUFFICIENT  
EVIDENCE



PRODUCT  
INFORMATION

## WHAT IS IT?

Alkaloid similar to nicotine.

## INDICATION

Smoking cessation and reduction of nicotine dependence cravings.

## POSOLGY AND METHOD OF ADMINISTRATION

Smoking should be stopped within the first five days of treatment because it may cause more severe adverse events to nicotine.

DAYS OF DOSAGE	DAILY DOSE	MAXIMUM RECOMMENDED TREATMENT
1st to 3rd day	1 tablet every 2 hours	6 tablets
4th to 12th day	1 tablet every 2-5 hours	5 tablets
13th to 16th day	1 tablet every 3 hours	4 tablets
17th to 20th day	1 tablet every 5 hours	3 tablets
21st to 25th day	1-2 tablets daily	Up to 2 tablets

**Special populations:** not recommended in >65 years of age, <18 years of age and in renal or hepatic impairment due to limited experience.

## EFFICACY

**Compared to placebo:** in a meta-analysis including two clinical trials (911 patients) with a follow-up of at least six months, cytisine was significantly more effective than placebo, increasing the probability of smoking cessation more than three times (RR=3.29, 95%CI 1.84 to 5.90).<sup>1</sup> **Compared to varenicline:** in a randomised, open-label, non-inferiority (margin of 5%) clinical trial, cytisine for 25 days was compared with varenicline for 84 days in 1452 patients. Abstinence rates at six months were 11.7% and 13.3% respectively, falling to demonstrate non-inferiority to varenicline.<sup>2</sup> **Compared to nicotine replacement therapy (NRT):** in a randomised, open-label trial with 1310 patients, continuous abstinence at six months was greater with cytisine than with NRT (22% vs. 15%).<sup>3</sup>

## RISKS

The most frequently reported adverse reactions ( $\geq 1/10$ ) were gastrointestinal disorders, increased appetite, weight gain, dizziness, irritability, mood changes, anxiety, sleep disorders, headache and difficulty in concentration, tachycardia, hypertension, rash, myalgia and fatigue. In clinical trials vs. placebo, the most frequent adverse events were gastrointestinal disorders (12% vs. 7.2%).<sup>1</sup> In the clinical trial vs. NRT, nausea, vomiting, and sleep disorders were more frequent with cytisine.<sup>3</sup> **Contraindications:** Unstable angina, recent myocardial infarction, arrhythmia, history of stroke, pregnancy and lactation. **Caution:** Smoking or use of nicotine-containing products concomitantly with cytisine may cause more severe adverse events. Do not take with anti-tuberculosis drugs. It is currently unknown whether cytisine may reduce the effectiveness of systemically acting hormonal contraceptives.

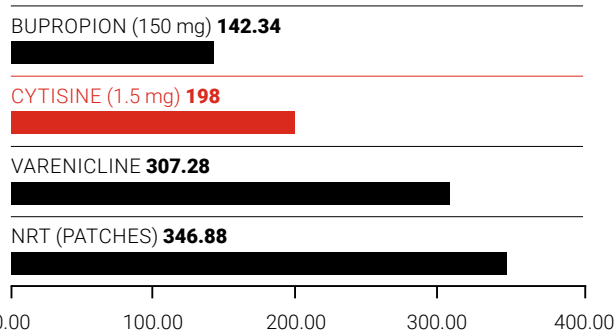
## PLACE IN THERAPEUTICS

Possible alternative to varenicline after NRT failure.

## PRESENTATIONS

Todacitan<sup>®</sup> EFG 1.5 mg 100 tablets (198 €). Not funded by the Spanish National Health System.

### Complete treatment cost (euros)



1. Hajek P, McRobbie H, Myers K. Efficacy of cytisine in helping smokers quit: systematic review and meta-analysis. Thorax. 2013; 68:1037-1042. <https://dx.doi.org/10.1136/thoraxjnl-2012-203035>

2. Courtney RJ, McRobbie H, Tutka P, et al. Effect of Cytisine vs Varenicline on Smoking Cessation: A Randomized Clinical Trial. JAMA. 2021; 326(1):56-64. <https://dx.doi.org/10.1001/jama.2021.7621>

3. Walker N, Howe C, Glover M, McRobbie H, et al. Cytisine versus nicotine for smoking cessation. N Engl J Med. 2014; 371(25):2353-62. <https://dx.doi.org/10.1056/NEJMoa1407764>