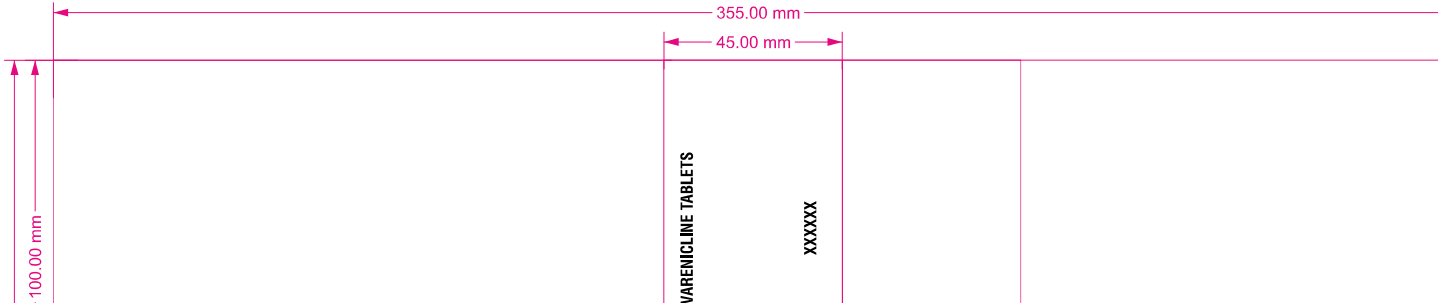




HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VARENICLINE TABLETS safely and effectively.

Full Prescribing Information for VARENICLINE TABLETS.

VARENICLINE TABLETS, for oral use

Initial U.S. Approval: 2006

INDICATIONS AND USAGE

Varenicline tablets are a nicotine receptor partial agonist indicated for use as an aid to smoking cessation treatment. (1 and 2.1)

DOSAGE AND ADMINISTRATION

- Begin varenicline tablets dosing one week before the date set by the patient to stop smoking.
- Alternatively, the patient can begin varenicline tablets dosing and then quit smoking between days 8 and 25 of treatment. (2.1)
- Starting Week: 0.5 mg once daily for days 1–3 and 0.5 mg twice daily on days 4–7. (2.1)
- Continuing Weeks: 1 mg twice daily for 1 and 2 weeks. (2.1)
- An additional 12 weeks of treatment is recommended for successful outcomes to increase likelihood of long-term abstinence. (2.1)
- Consider a gradual approach to quitting smoking with varenicline tablets for patients who are sure they are not able or willing to quit abruptly. Patients should begin varenicline tablets dosing and reduce smoking by 50% from baseline within the first four weeks, by an additional 50% in the next four weeks, and continue reducing with the goal of reaching complete abstinence by 12 weeks. Continue treatment for an additional 12 weeks, for a total of 24 weeks. (2.1)
- Severe Rash/Allergic Reaction (estimated clearance less than 30 mL/min): Begin with 0.5 mg once daily and titrate to 0.5 mg twice daily. For patients with end-stage renal disease undergoing hemodialysis, a maximum of 0.5 mg daily may be given if tolerated. (2.2)
- Consider dose reduction for patients who cannot tolerate adverse effects. (2.1)
- Another attempt at treatment is recommended for those who fail to stop smoking or relapse during factors contributing to the failed attempt that have been addressed. (2.1)

FULL PRESCRIBING INFORMATION: CONTRAINDICATIONS

1. INDICATIONS AND USAGE

2. DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage for Adults

2.2 Dosage in Special Populations

3. DOSAGE FORMS AND STRENGTHS

4. CONTRAINDICATIONS

5. WARNINGS AND PRECAUTIONS

5.1 Neuropsychiatric Adverse Events including Suicidality

5.2 Seizures

5.3 Interaction with Alcohol

5.4 Accidental Injury

5.5 Cardiovascular Events

5.6 Serotonin Syndrome

5.7 Angiodema and Hypersensitivity Reactions

5.8 Serious Skin Reactions

5.9 Nausea

6. ADVERSE REACTIONS

6.1 Clinical Trial Experience

6.2 Postmarketing Experience

7. DRUG INTERACTIONS

7.1 Use with Other Drugs for Smoking Cessation

7.2 Effect of Smoking Cessation on Other Drugs

7.3 USE IN SPECIAL POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.3 Geriatric Use

8.6 Renal Impairment

9. DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

9.3 Dependence

10. OVERDOSAGE

11. DESCRIPTION

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacokinetics

12.3 Pharmacodynamics

12.4 Toxicology

12.5 Immunogenicity

12.6 Microbiology

12.7 Pharmacovigilance

12.8 Clinical Studies

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