

FIRST TIME GENERIC APPROVAL

Brand Name	Chantix™
Generic Name	varenicline
Drug Manufacturer	Pfizer INC

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

July 15,2021

LAUNCH DATE

N/A

REVIEW DESIGNATION

Priority

TYPE OF REVIEW

New Drug Application (NDA): 021928

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Varenicline is indicated as an aid to smoking cessation treatment.

MECHANISMS OF ACTION

Varenicline binds with high affinity and selectivity at $\alpha 4\beta 2$ neuronal nicotinic acetylcholine receptors. The efficacy of varenicline in smoking cessation is believed to be the result of it's activity at a sub-type of the nicotinic receptor where its binding produces agonist activity, while simultaneously preventing nicotine binding to $\alpha 4\beta 2$ receptors.

DOSE FORM AND STRENGTH

0.5mg,1 mg Base tablet oral.

DOSE & ADMINISTRATION

Varenicline should be taken after eating and with a full glass of water. The recommended dose of varenicline is 1 mg twice daily following a 1-week titration as follows:

Days 1 – 3:	0.5 mg once daily
Days 4 – 7:	0.5 mg twice daily
Day 8 – End of treatment:	1 mg twice daily

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