Tobacco Cessation Toolkit

Summary of Tobacco Cessation Pharmacotherapy – Non-Nicotine

This resource includes summary charts for use in providing non-Nicotine Replacement Therapy pharmacotherapy.

Bupropion SR

Cost: $2 to $3 per day	Dosage: 150 mg SR tablets
Approved Indications	**Dosing**

• Indicated as smoking cessation treatment in conjunction with behavioural modification.
• Also approved for use in combination with nicotine replacement therapy.
• Prior to deciding to prescribe a non-nicotine treatment, thorough consideration should be given to the treatment option of nicotine replacement therapy alone.
	• Starting one to two weeks prior to the target quit date:
	  • 150 mg in the morning for three days, followed by 150 mg twice daily, with dosages at least eight hours apart.
	  • Taken for 7 to 12 weeks; up to six months can be considered post-quit.

Labelled Precautions/Indications	

Pregnancy
• Pregnant women should be encouraged to quit without medication.
• Bupropion has not been shown to be effective for tobacco cessation in pregnant women.
• Bupropion has not been evaluated in breastfeeding patients.
• Bupropion is an FDA pregnancy Class C agent.
 	
Cardiovascular disease
• Generally well-tolerated; occasional reports of hypertension.
 	
Seizure risk
• Contraindicated in history of seizures or eating disorders, with concurrent use of another form of bupropion, or use of a MAO inhibitor in the past 14 days.
• Extreme caution in those with risk factors for seizures, including:
  – excessive alcohol use
  – concurrent drug abuse
  – history of head trauma, CNS tumour
  – presence of severe hepatic impairment
  – use of concomitant medications that lower seizure threshold (e.g., antipsychotics, antidepressants, lithium, amantadine, theophylline, systemic steroids, quinolone antibiotics, antimalarials)
  – use of over-the-counter stimulants or anorectics
  – diabetes treated with oral hypoglycemics or insulin
 	
Psychiatric warnings
• Agitation-type events have been reported in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others.
• The agitation-type events include akathisia, agitation, disinhibition, emotional lability, hostility, aggression and depersonalization.	

- In some cases, the events occurred within several weeks of starting treatment.

Clinical monitoring for psychiatric symptoms is recommended.

Varenicline

Cost: $3.50 to $4.50 per day	Dosage: 0.5 mg,1 mg

Approved Indications

- Smoking-cessation treatment in adults in conjunction with smoking-cessation counselling.

Can be used in combination with bupropion.

Dosing

Setting a Quit Date

There are three different ways to set the quit date with varenicline

- Fixed Quit Approach: The patient sets a date to stop smoking and varenicline dosing is started 1-2 weeks before this date.
- Flexible Quit approach:
  The patient begins varenicline and then quits smoking between days 8 and 35 of treatment (i.e., between Weeks 2 and 5)
- Gradual Quit approach: The patient starts taking varenicline with a goal to quit smoking by end of 12 weeks of treatment. The patient should gradually reduce smoking during the first 12 weeks of treatment such as 50% reduction or more by 4 weeks of treatment, 75% or more by 8 weeks to reach 100% by 12 weeks

Dosing

0.5 mg daily for three days, then 0.5 mg twice daily for four days.

- The dosage may be increased to 1 mg twice daily on day eight, but 0.5 mg twice daily may also be effective.
- The choice of dosing regimen from day 8 onward should be based on physician judgment and patient preference.

Duration of Treatment

- Fixed Quit and Flexible Quit Approaches: For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with varenicline may be considered.

Gradual Quit: Patients who follow the gradual quit approach (12 week) should be treated with varenicline for 24 weeks.

Labelled Precautions/Indications

Psychiatric safety

- ”Black box” type warnings about neuropsychiatric adverse effects in varenicline product monographs were removed by the EMA, FDA and most recently by Health Canada in February 2017.
- The need for ongoing assessment of monitoring for any changes in behavior or thinking that are not typical for the patient remains during any quit attempt for patients with or without a history of psychiatric disorders given that these changes can occur with or without medication use.
- Psychiatric warnings remain in the product monograph as follows: There have been post-marketing reports of serious neuropsychiatric symptoms in patients being treated with varenicline,

including anxiety, psychosis, mood swings, depressed mood, agitation, aggression, hostility, changes in behavior or thinking, suicidal ideation, suicidal behavior and suicide, as well as worsening of pre-existing psychiatric disorder (previously diagnosed or not). Not all patients had stopped smoking at the time of onset of symptoms, and not all patients had known pre-existing psychiatric illness, or were using concomitant CNS drugs.

- Recommendations: Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking, with or without treatment.
- Pre-existing Psychiatric Disorder or Symptoms:
    - Smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression, anxiety). Patients with a history of psychiatric symptoms should be monitored for worsening or new symptoms when attempting to quit smoking, regardless of how well controlled symptoms may be when starting smoking cessation treatment. Patients should be instructed to report strongly a typical and concerning symptoms to their healthcare provider, so that dose adjustments of psychiatric medications or varenicline may be considered.

General

- Patients should be informed that if they experience thoughts, moods or behaviours that are strongly atypical and concerning while on smoking-cessation medication, including varenicline, the medication should be discontinued immediately, with urgent medical help sought as needed, and the symptoms reported to their healthcare provider.

Cardiovascular disease

- Patients should be advised to notify a health-care provider of any new or worsening symptoms of cardiovascular disease.

Pregnancy

- Pregnant women should be encouraged to quit without medication.
- Varenicline has not been shown to be effective for tobacco cessation in pregnant women.
- Varenicline is an FDA pregnancy Class C agent.
- Varenicline has not been evaluated in breastfeeding patients.

Renal impairment

- Caution for patients with significant renal impairment (creatinine clearance < 30 ml per min) or who are on dialysis.
- Doses should be reduced for these patients.

Activities

- May experience impairment of the ability to drive or operate heavy machinery.