

Comparison Of Current Pharmacotherapy For Nicotine Dependence Treatment**

For the
treatment of
Nicotine
Dependence

| Product | OTC Nicotine Patch | OTC Nicotine Gum and Lozenge | | Rx Nicotine Spray | Rx Nicotine Inhaler | Rx Bupropion HCl SR Tablet | Varenicline |
|---|--|--|---|--|--|--|---|
| BRAND NAME | NICODERM [®] CQ | NICORETTE [®] (gum) | COMMIT [®] (lozenge) | NICOTROL [®] NS | NICOTROL [®] INHALER | ZYBAN [®] | CHANTIX [®] |
| PRODUCT STRENGTHS | 24 mg, 14 mg, 7 mg | 2 mg, 4 mg | | 10 mg/ml | 10 mg/cartridge | 150 mg tablets | 0.5 mg, 1 mg tablets |
| INITIAL DOSING | 1 patch/24 hours | 1 piece of gum/lozenge every 1–2 hours | | 1–2 doses/hour (1 dose = 2 sprays per nostril) | 6–16 cartridges/day | 150 mg/day (days 1–3) 300 mg/day (days 4+) | .05 mg/day (days 1–3) .05 mg/2x/day (days 4–7) 1.0 mg/2x/day (days 8+) |
| MAX DOSING | same as above | 24 piece of gum/24 hours | 20 lozenges/24 hours | 5 doses/hour or 40 doses/day | 16 cartridges/day | 300 mg/day | 2 mg/day |
| TIME TO PEAK PLASMA LEVEL | 5–10 hours | 20–30 minutes | | 5–7 minutes | 15 minutes | 3 hours | 3–4 hours |
| RECOMMENDED TREATMENT DURATION | 8 weeks | Up to 12 weeks | | 3–6 months | Up to 6 months, taper during final 3 months | 7–12 weeks after quit date | Initiate 1 week before quit date. Continue up to 12 weeks. For those quit at 12 weeks, another 12 week course may be recommended |
| ADVERSE REACTIONS | 50% experience mild skin reactions (rotate and use steroid cream); vivid dreams, sleep disturbances while on the patch for 24 hours (remove at bed time) | Mouth soreness, hiccups, dyspepsia and, for gum, jaw ache (usually mild and transient; correct technique) | | Local transient irritation in the nose and throat, watery eyes, sneezing and cough, runny nose | 40% experience mouth and throat irritation (resolved through regular use); dyspepsia | Dry mouth; insomnia (avoid bedtime dose); shakiness and skin rash | Nausea, sleep disturbance, constipation, flatulence, and vomiting. Do not use with NRT: increases adverse effects. |
| UNIQUE PRODUCT CONTRAINDICATIONS (GENERAL NRT CONTRAINDICATIONS ON OTHER SIDE) | Severe eczema or other skin diseases which may be exacerbated by the patch; allergy to adhesive tape | Severe TMJ disease or other jaw problems; presence of dentures or other dental appliances; mouth or throat irritation from any other cause | Mouth or throat irritation from any other cause | Asthma, rhinitis, nasal polyps, or sinusitis | Allergy to menthol | Seizure disorder; current use of Wellbutrin/bupropion; current or prior dx of bulimia or anorexia nervosa; concurrent or recent use of MAO inhibitors; bupropion allergy | In patients on renal dialysis or severe renal insufficiency (GFR<30ml/mn), must reduce dose to 0.5mg daily. All patients should be observed for neuropsychiatric symptoms including changes in behavior, agitation, depressed mood, suicidal ideation, and suicidal behavior. |
| CONSUMER INFORMATION | 1-800-834-5895 www.nicotrolCQ.com | 1-800-419-4766 www.nicorette.com | 1-888-569-1743 www.commitlozenge.com | 1-800-699-5765 www.nicotrol.com | 1-800-699-5765 www.nicotrol.com | 1-800-U-CAN-QUIT www.Zyban.com | 1-877-CHANTIX www.chantix.com |
| COST/DAY (PRICES AS OF 4/00) | ~\$3.60 | ~\$5.20–\$6.20/12 pieces | ~6.50–\$7.50/12 lozenges | ~\$5.50 for 12 doses | ~\$8.00 for 6 cartridges | ~\$3.40 | \$3–6 |

WHY SHOULD YOU RECOMMEND OR PRESCRIBE PHARMACOTHERAPY FOR YOUR PATIENTS WHO SMOKE?

Because there is strong evidence that pharmacotherapies are effective for a broad range of smokers. Use of NRT and/or bupropion approximately *doubles* long-term quit rates.

WHICH OF YOUR PATIENTS SHOULD USE PHARMACOTHERAPY?

Recommend pharmacotherapy to ALL patients who smoke AND:

- Are interested in quitting AND
- Do not have a medical contraindication to NRT or bupropion (see Precautions/Contraindications)*

* Little research is available on the use of pharmacotherapy with patients who smoke less than 10–15 cigarettes per day. For these light smokers a lower starting dose of the nicotine patch or gum could be considered. No adjustments are necessary when using bupropion SR.

** Inclusion of this adult dosage chart is strictly for the convenience of the prescribing provider. Please consult the Physicians' Desk Reference for complete product information and provides information on the appropriate use of nicotine replacement therapy (NRT) and bupropion SR (Zyban®). QuitWorks was developed by the Massachusetts Department of Public Health (MDPH) in collaboration with Massachusetts health plans and has been in operation since 2002. The program has been adopted by the Rhode Island Department of Health with permission of the Massachusetts Department of Public Health. The Pharmacotherapy Guide was developed by the Center for Tobacco Prevention and Control, Division of Preventive and Behavioral Medicine, University of Massachusetts Medical School. Updated in 2008.

Choice And Use Of Pharmacotherapy

NICOTINE PATCH

May be the best choice of NRT for most patients. Adherence is usually better than with nicotine gum, spray or inhaler.

Dose & Technique:

- Start most smokers of 10–15 cigarettes or more/day at the highest dose patch.
- If vivid dreams or sleep disturbances are experienced, remove at bedtime.
- Consider lower starting doses in smokers of less than 10 cigarettes/day.
- A new patch is applied each morning to the upper torso.

Treatment Duration:

- Treatment of 8 wks or less has been shown to be as effective as longer treatment.
- Tapering dose after 4 wks is generally recommended for most smokers.
- Use for longer duration if unsuccessful on shorter duration.
- Use for longer duration at higher dose for heavier smokers.

NICOTINE GUM or NICOTINE LOZENGE

May be a good choice for patients who:

- Have not been successful on the patch.
- Prefer the gum or lozenge for personal reasons
- Have had a severe skin reaction to the patch.

Dose & Technique:

- Specify 2 mg gum for those who smoke less than 25 cigarettes/day. Specify 4 mg gum for more highly dependent smokers (25 or more cigarettes/day, smoking within 30 min of awakening, and/or those finding it difficult to refrain from smoking where it is forbidden).
- Specify 2 mg lozenge for those whose first cigarette of the day is more than 30 min after awakening. Specify 4 mg lozenge for those who smoke within 30 min after awakening.
- Recommend patient use one piece of gum or one lozenge every 1–2 hrs (many patients use less than is needed for optimum effect).
- Maximum dose: 24 pieces/day of either the 2 mg or 4 mg gum or 20 lozenges/day of either the 2 mg or 4 mg lozenge.
- Proper use is critical to effectiveness. For gum, emphasize the importance of alternating chewing and parking each piece for 30 min. For lozenge, patient should allow it to dissolve slowly, occasionally moving it from one side of the mouth to another.
- Advise patient not to consume acidic beverages or food 15 min before and during gum and lozenge use.

Treatment Duration:

- Recommended duration of therapy is up to 12 wks.

NICOTINE NASAL SPRAY

Nicotine nasal spray is available by prescription only. It provides the most rapid nicotine delivery of all NRT products and provides greater capacity for self-titration of dose. Dependency potential is greater with the spray than with nicotine gum or the nicotine patch.

Dose & Technique:

- Usual single dose is two sprays, one in each nostril.
- Start patient at 1–2 doses/hour.
- Maximum dose: 5 doses/hour or 40 doses/day.

Treatment Duration:

- Recommended duration of therapy is 3–6 months.

NICOTINE INHALER

The nicotine inhaler is available by prescription only. It addresses pharmacological, behavioral and sensory stimuli aspects of smoking. The nicotine is absorbed through the lining of the mouth.

Dose & Technique:

- A dose consists of a puff or inhalation.
- Each cartridge delivers 4 mg of nicotine over 80 inhalations; only 2 mg are actually absorbed (this is the equivalent of about 2 cigarettes).
- Advise patient not to drink acidic beverages 15 min before and during the inhalation.
- Best effects are achieved by frequent puffing.
- Recommended dosage is 6–16 cartridges/day; patients may self-titrate to the level of nicotine they require.
- Maximum dose: 16 cartridges/day.

Treatment Duration:

- Recommended duration of therapy is up to 6 months.
- Instruct patient to taper dosage during last 6–12 wks of treatment.

Precautions & Contraindication for all NRT Products

(See table on back for unique product contraindications and bupropion contraindications.)

Cardiovascular Disease

Although not an independent risk factor for acute myocardial events, NRT should be used only after consideration of risks and benefits among particular cardiovascular patient groups including:

- Those in immediate (within 4 weeks) postmyocardial infarction period.
- Those with serious arrhythmias.
- Those with severe or worsening angina pectoris.

Peptic Ulcer Disease

- Nicotine may delay healing of active ulcers.
- No studies are available on the effects of NRT on ulcer disease.
- Weigh risks and benefits of NRT in patients with active ulcer.

Other Conditions Which May Contraindicate NRT

- Severe renal failure.
- Active hyperthyroidism.
- Poorly controlled insulin-dependent diabetes.
- Severely uncontrolled hypertension.
- Peripheral vascular disease.

Children & Adolescents

NRT should be considered in children and adolescents only when there is clear evidence of nicotine dependence and clear desire to quit. Degree of dependence and body weight should be considered when selecting NRT dose.

Pharmacotherapy & Pregnancy

There are no adequate studies on the safety of pharmacotherapy in pregnant women. Pregnant smokers should be encouraged to quit using behavioral interventions before pharmacological approaches are used. Pharmacotherapy is recommended only if the increased likelihood of smoking cessation clearly outweighs the risk of pharmacotherapy.

BUPROPION SR

May be a good choice for patients who:

- Do not have a history of seizures.
- Prefer an alternative to nicotine replacement.

Dose & Technique:

- Maximum dose is 300 mg/day, given as 150 mg twice daily.
- Dosing should begin at 150 mg/day given every day for the first 3 days, followed by a dose increase for most patients to the recommended dose of 300 mg/day. Interval of at least 8 hours between successive doses.
- Treatment with bupropion should be initiated while the patient is still smoking; approximately one week of treatment is required to achieve steady-state blood levels. "Quit attempt should occur during second week of treatment."
- Bupropion SR can be used in combination with NRT.

Treatment Duration:

- Treatment should be continued for 7–12 weeks following quit date.
- Patients who have not made significant progress towards abstinence by the seventh week of therapy are unlikely to successfully quit during this attempt and treatment should be discontinued.
- For maintenance therapy, consider 150 mg b.i.d. for up to 6 months.
- Dose tapering is not required when discontinuing treatment.

Combination Therapy

There is limited evidence that combining patch and other NRTs or patch and bupropion may slightly increase quit rates over monotherapy. Combination therapy may be considered in persons who have failed on monotherapy or are heavily addicted.

Note Regarding Psychiatric Conditions

Although psychiatric conditions (e.g., depression, alcohol abuse and dependence) place smokers at increased risk for relapse to smoking, smoking cessation treatments can be effective, and NRT and bupropion should be considered as part of a comprehensive approach to cessation. One of the benefits of NRT and bupropion is that they abate mood-related withdrawal symptoms but produce relatively few adverse effects.

VARENICLINE

Dose & Technique:

- Maximum dose is 2.0 mg/day, given as 1.0 mg twice daily.
- Dosing should begin at 0.5 mg/day given every day for the first 3 days, followed by a dose increase to 0.5 mg taken morning and evening for the next 4 days. On Day 8 and beyond, the recommended dose is 1.0 mg b.i.d.
- Treatment with varenicline should be initiated while the patient is still smoking; approximately one week of treatment is required to achieve steady-state blood levels. Quit attempt should occur during second week of treatment. Patients should be encouraged to continue to attempt to quit if they have early lapses after quit day.

Treatment Duration:

- Treatment should be continued for up to 11 weeks following quit date.
- Patients who are abstinent at week 12 may benefit from an additional course of 2.0 mg b.i.d. for up to twelve weeks.
- Dose tapering is not required when discontinuing treatment.

Combination Therapy

Varenicline should not be used in combination with NRT due to increases in adverse affects.

Note Regarding Psychiatric Conditions

Serious neuropsychiatric symptoms have occurred in patients being treated with CHANTIX. Some cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking; however, some of these symptoms have occurred in patients who continued to smoke. All patients being treated with CHANTIX should be observed for neuropsychiatric symptoms including changes in behavior, agitation, depressed mood, suicidal ideation and suicidal behavior.

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