

More than 1 way
to stop smoking

New Indication
Quitting Gradually
(REDUCE-TO-QUIT™)

nicorette®

REDUCE-TO-QUIT™

Dosing Suggestions for the Quitting Gradually Program**

| | |
|--------------------|--|
| 0-1½ months | start replacing cigarettes with NICORETTE®// |
| 1½-4 months | 50% reduction in daily cigarettes |
| 4-6 months | attempt to quit |

Stop-to-Quit

Dosing Suggestions for the Quitting Abruptly Program**

| | |
|-------------------|---|
| Month 1 | |
| weeks 1 & 2 | 10-20 pieces// |
| weeks 3 & 4 | 8-15 pieces |
| Month 2 | 4-10 pieces (1 every 2 to 4 hours) |
| Month 3 | 2-5 pieces (1 every 4 to 8 hours) |
| Months 4-6 | chew 1 piece if the urge to smoke returns |

//Use NICORETTE® as needed, not exceeding 20 pieces of gum per day
**Take 2 mg if you smoke >30 minutes after waking up. Take 4 mg if you smoke <30 minutes of waking up.

Temporary Abstinence from Smoking

NICORETTE® Gum can be used in cases which a smoker temporarily refrains from smoking.

NICORETTE® should be used as an adjunct to smoking cessation programs and the dose should be individualized. Patients should chew one piece of gum when they have the urge to smoke. Most patients require 10-12 pieces/day for the 1st month with a maximum of 20 pieces/day. The dose should be gradually reduced by one or more pieces every 4-7 days. Use beyond 6 months is not recommended. Please consult prescribing information for complete dosage and administration instructions.

NICORETTE® Gum is a stop smoking aid designed to provide partial substitution for the nicotine in cigarette smoke and is intended as a temporary aid in cushioning the patient against the psychopharmacological effects of nicotine withdrawal symptoms. NICORETTE® Gum is indicated in smoking cessation and can be used as an adjunct to a smoking cessation program. It can be used for quitting abruptly (smokers set a quit date and use NICORETTE® Gum to control their nicotine cravings and withdrawal symptoms) or quitting gradually (for smokers unable or not ready to quit abruptly, NICORETTE® Gum can be used to gradually reduce the number of cigarettes smoked per day prior to making a quit attempt). It is also indicated for temporary abstinence, in which a smoker temporarily refrains from smoking. See Product Monograph for important patient selection information.

NICORETTE® Gum is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container, patients in the immediate post-myocardial infarction period, patients with life-threatening arrhythmias, patients with severe or worsening angina pectoris, patients with active temporomandibular joint disease, pregnant or nursing women, non-smokers and children under 18 years of age.

The amounts of nicotine that are tolerated by adult smokers can produce symptoms of poisoning and could prove fatal if ingested by children or pets. Patients should be warned to keep NICORETTE® Gum out of the reach of children and pets. Simultaneous smoking and chewing of NICORETTE® Gum should be avoided. Incidence of side effects with NICORETTE® Gum varies considerably. It can cause headache, light-headedness, hiccups, upset stomach and other stomach problems, especially if chewed too quickly or not chewed correctly, burping, increased salivation, jaw ache, unusual taste in mouth, gingivitis, irritated or inflamed tongue, bleeding gums, tongue discoloration and sores. Other common side effects include mouth or throat soreness.

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nicorette®



07-067

Help your patients make
molehills out of a mountain



Recommend REDUCE-TO-QUIT™ with NICORETTE®

It was demonstrated that people on NICORETTE® Gum were **over 4X more successful at quitting** vs. placebo (n=37/800 vs. n=8/796). The successful NICORETTE® reducer† had a **36.7% likelihood of quitting long-term** (being quit at 12 mths; n=37/101).‡



A new way to look at...
nicorette®

†Smokers who were successful at reducing their cigarette consumption at 4 months.
‡Pooled results from 4 placebo-controlled, double-blind trials in healthy smokers (n=1,596) motivated to reduce their smoking. Patients were randomized to receive either the gum (n=800) or placebo (n=796).¹

nicorette[®] gum

Nicotine Polacrilex Gum USP
2 mg, 4 mg
Stop Smoking Aid

INDICATIONS AND CLINICAL USE

NICORETTE[®] Gum (nicotine polacrilex) is a stop smoking aid designed to provide partial substitution for the nicotine in cigarette smoke and is intended as a temporary aid in cushioning the patient against the psychopharmacological effects of nicotine withdrawal symptoms. NICORETTE[®] Gum is indicated in:

1. Smoking Cessation

NICORETTE[®] Gum can be used as an adjunct to a smoking cessation program. It can be used in the following ways:

A. Quitting Abruptly (Stop-to-Quit)

Smokers set a quit date and use NICORETTE[®] Gum to control their nicotine cravings and withdrawal symptoms.

B. Quitting Gradually (REDUCE-TO-QUIT[™])

For smokers unable or not ready to quit abruptly, NICORETTE[®] Gum can be used to gradually reduce the number of cigarettes smoked per day prior to making a quit attempt.

2. Temporary Abstinence from Smoking

Although smoking cessation is preferable, NICORETTE[®] Gum can also be used in cases in which a smoker temporarily refrains from smoking. NICORETTE[®] Gum can be used during smoke free periods, for example in smoke free areas or in other situations when the patient wishes to avoid smoking.

Before initiating treatment with NICORETTE[®] Gum, the physician or pharmacist should determine the patient's level of nicotine dependence using the Fagerström Nicotine Tolerance Scale shown below.

Instructions for Use of the Fagerström Scale

Assign the appropriate score indicated in each column according to the patient's answer to the questions (note that not all questions have an answer in Column C). The highest possible score is 11.

If the score is 6 or less, NICORETTE[®] Gum (2 mg) is recommended for use. If the score is 7 or greater, NICORETTE[®] Gum (4 mg) should be used.

The Fagerström Nicotine Tolerance Scale

| | A=0 points | B=1 point | C=2 points | Score |
|--|---|------------------------------|---------------------------|-------|
| How soon after you wake up do you smoke your first cigarette? | After 30 minutes | Within 30 minutes | | |
| How many cigarettes a day do you smoke? | 1-15 | 16-25 | 26 or more | |
| Does the brand you smoke have a low, medium or high nicotine content? | Low, less than 0.4 mg | Medium, between 0.5-0.8 mg | High, greater than 0.9 mg | |
| Which of all the cigarettes you smoke in a day is the most satisfying one? | Any other than the first one in the morning | The first one in the morning | | |
| Do you smoke more during the morning than during the rest of the day? | No | Yes | | |
| Do you smoke when you are so ill that you are in bed most of the day? | No | Yes | | |
| Do you find it difficult to refrain from smoking in places where it is forbidden, such as the library, theatre, doctor's office? | No | Yes | | |
| How often do you inhale the smoke from your cigarette? | Never | Sometimes | Always | |
| | | | Score | |

CONTRAINDICATIONS

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the product monograph.
- Patients in the immediate post-myocardial infarction period, patients with life-threatening arrhythmias, and patients with severe or worsening angina pectoris.
- Patients with active temporomandibular joint disease
- Pregnant women (See WARNINGS)
- Breast feeding mothers, as nicotine is excreted in breast milk (See WARNINGS)
- Non-smokers and children under 18 years of age (See WARNINGS)

WARNINGS AND PRECAUTIONS

General

The amounts of nicotine that are tolerated by adult smokers can produce symptoms of poisoning and could prove fatal if ingested by children or pets. Patients should be warned to keep NICORETTE[®] Gum out of the reach of children and pets. Simultaneous smoking and chewing of NICORETTE[®] Gum should be avoided.

NICORETTE[®] Gum should be used with caution in patients with oral or pharyngeal inflammation and in patients with a history of esophagitis or peptic ulcer.

The NICORETTE[®] Gum dosage form dictates that it be used with caution in patients whose dental problems might be exacerbated by chewing gum. In such patients, prior dental evaluation may be advisable.

NICORETTE[®] Gum is sucrose-free (sweetened with xylitol and acesulfame potassium) and has been formulated to minimize stickiness. As with other gums, however, the degree to which NICORETTE[®] Gum may stick to dentures, dental caps or partial dentures may depend on the materials from which they are made and other factors such as amount of saliva produced, possible interaction with denture adhesives, denture cleaning compounds, dryness of mouth due to other causes and salivary constituents. Should an excessive degree of adherence to dental work occur, there is the possibility that as with other gums NICORETTE[®] Gum may damage dental work. If this should occur, the patient should discontinue its use and consult a physician or dentist.

Carcinogenesis and Mutagenesis

Nicotine was not mutagenic in the Ames Salmonella test. Literature reports indicate that nicotine is neither an initiator nor a tumour-promoter in mice, and there is inconclusive evidence to suggest that cotinine, an oxidized metabolite of nicotine, may be carcinogenic in rats. Cotinine was not mutagenic in the Ames Salmonella test.

Studies have shown a decrease of litter size in rats treated with nicotine during the time of fertilization.

Cardiovascular

In patients with certain cardiovascular and endocrine diseases, the risks of using nicotine should be carefully weighed against the benefits of including NICORETTE[®] Gum in a smoking cessation program.

Patients with coronary heart disease (history of myocardial infarction and/or angina pectoris), serious cardiac arrhythmias, or vasospastic diseases (Buerger's disease, Prinzmetal variant angina) should be carefully screened and evaluated before NICORETTE[®] Gum is used. Occasional reports of tachyarrhythmias occurring in association with the use of NICORETTE[®] Gum have been reported; therefore, if an increase in cardiovascular symptoms occurs with the use of NICORETTE[®] Gum it should be discontinued.

Cigarette smoking is felt to play a perpetuating role in hypertension. Therefore, NICORETTE[®] Gum should be used in patients with systemic hypertension only when the benefits of including NICORETTE[®] Gum in a smoking cessation program outweigh the risks.

Dependence/Tolerance

The sustained use of NICORETTE[®] Gum by former smokers is not to be encouraged because the chronic consumption of nicotine is toxic and addicting. The relative risks of a possible return to smoking should however be weighed against the continued long-term use of NICORETTE[®] Gum.

Endocrine and Metabolism

As the action of nicotine on the adrenal medulla (release of catecholamines) does not appear to be affected by tolerance, NICORETTE[®] Gum should be used with caution in patients with hyperthyroidism, pheochromocytoma or insulin-dependent diabetes.

Gastrointestinal

Cigarette smoking is felt to play a perpetuating role in peptic ulcer disease. Therefore, NICORETTE[®] Gum should be used in patients with peptic ulcer (active or inactive) only when the benefits of including NICORETTE[®] Gum in a smoking cessation program outweigh the risks.

Renal

NICORETTE[®] Gum should be used with caution in patients with severe renal insufficiency.

Special Populations

Pregnant Women: Use of cigarettes or NICORETTE[®] Gum during the last trimester has been associated with a decrease in fetal breathing movements. These effects may be the result of decreased placental perfusion caused by nicotine. Rare reports of miscarriages have been received, and a relationship to drug therapy as a contributing factor cannot be excluded. Studies in pregnant rhesus monkeys have shown that maternal nicotine administration produced acidosis, hypoxia and hypercarbia in the fetus.

NICORETTE[®] Gum, therefore, should generally not be used in women who are or may become pregnant, and female patients should be advised to take adequate precautions to avoid becoming pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Nursing Women: Nicotine passes freely into the breast milk. Because of the potential for serious adverse reactions from nicotine in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. (See CONTRAINDICATIONS)

Pediatrics: Safety and effectiveness in children and adolescents who smoke have not been evaluated. The use of NICORETTE[®] Gum is not recommended in smokers under 18 years of age. (See CONTRAINDICATIONS)

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Adverse reactions reported in association with the use of NICORETTE[®] Gum include both local effects and systemic effects representing the pharmacological action of nicotine.

Clinical Trial Adverse Drug Reactions

Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

Cessation Studies

Local Side Effects – NICORETTE[®] Gum (2 mg) & NICORETTE[®] Gum (4 mg)

Mechanical effects of gum chewing include traumatic injury to oral mucosa or teeth, adhesion to dentures/teeth, jaw ache, and eructation secondary to air swallowing. These side effects may be minimized by modifying chewing technique. Oral mucosa changes such as stomatitis and throat irritation, glossitis, gingivitis, pharyngitis, and aphthous ulcers, in addition to changes in taste perception, can occur during smoking cessation efforts with or without the use of NICORETTE[®] Gum.

Oral adverse events occurring with a frequency of 1% or greater in 1801 patients using NICORETTE[®] Gum (4 mg) in two clinical trials were throat irritation 5%, stomatitis (excluding aphthous and ulcerative stomatitis) 4%, taste perversion 3%, tooth disorder (e.g., occlusal stress as a result of chewing, loosening of fillings, gum sticking to dentures, etc.) 2%, aphthous stomatitis 2%, gingivitis 1% and glossitis 1%.

Other oral events reported were gingival bleeding, taste loss, tongue discoloration and tongue ulceration.

Systemic Side Effects – NICORETTE[®] Gum (2 mg)

Although the types of systemic adverse drug effects seen in clinical trials are similar from one trial to the other, the incidence of individual effects varies considerably from trial to trial. In two well-controlled clinical trials (one performed in the United States and one in England) designed to evaluate the safety and efficacy of NICORETTE[®] Gum (2 mg) this variation was evident (see Table 1).

Table 1 - Adverse Event Incidence in Clinical Trials Performed in the U.S. and England

Due to its inherent variability, the list of adverse event incidences can

| | U.S. Trial n= 94 (%) | British Trial n= 58 (%) |
|---|-------------------------|----------------------------|
| Autonomic | | |
| Excessive salivation | 2.1 | - |
| CNS | | |
| Insomnia | 1.1 | - |
| Dizziness/light-headedness | 2.1 | 19.0 |
| Irritable/fussy | 1.1 | - |
| Headache | 1.1 | 24.1 |
| Gastrointestinal | | |
| Non-specific GI distress | 9.6 | - |
| Eructation | 6.4 | - |
| Indigestion | - | 41.4 |
| Nausea/vomiting | 18.1 | 31.0 |
| Reactions Referable to Mouth, Jaw or Teeth | | |
| Mouth or throat soreness | 37.2 | 56.9 |
| Jaw muscle ache | 18.1 | 44.8 |
| Other | | |
| Anorexia | 1.1 | - |
| Hiccups | 14.9 | 22.4 |

be used only as an indication of the relative frequency of adverse events reported in representative clinical trials. It cannot predict expected incidences of these effects during the course of usual medical practice.

Systemic Side Effects – NICORETTE[®] Gum (4 mg)

Adverse events that occurred in 1801 patients who participated in two clinical trials of NICORETTE[®] Gum (4 mg) are listed by body system. Incidences of 1% or greater are shown in brackets.

Cardiovascular: Chest pain (1%);

CNS: Headache (11%), dizziness (4%), insomnia (2%), fatigue (1%), abnormal dreaming, agitation, anxiety, apathy, depersonalization, drug dependence, emotional lability, hypoaesthesia, impaired concentration, irritability, light-headedness, migraine, nervousness, nightmare, sleep disorder, tremor;

Dermatologic: Acne, pruritus;

Gastrointestinal: Dyspepsia (9%), nausea (9%), abdominal pain (1%), diarrhea (1%), eructation (1%), flatulence (1%), vomiting (1%), abdominal distension, colitis, diverticulitis, gastritis, gastroesophageal reflux, increased salivation, non-specific gastrointestinal distress, peptic ulcer, ulcer;

Respiratory: Cough (1%), bronchitis, bronchospasm, congestion, epistaxis, laryngitis, nasal irritation, rhinitis, rhinorrhea, sinusitis;

Other: Hiccups (10%), pain (2%), dry mouth (1%), malaise (1%), abnormal lacrimation, abnormal serum folate test, allergic reaction, anorexia, arthralgia, back pain, dehydration, dysmenorrhea, dysphagia, dysphonia, earache, ear disorder, fever, halitosis, hot flushes, hypothyroidism, leg cramps, lymphadenopathy, mucus membrane disorder, myalgia, nail disorder, oliguria, sweating, thirst, vision abnormality.

Post-Market Adverse Drug Reactions

In addition to the reported effects in clinical trials, the following events have been reported:

Cardiovascular: Edema, flushing, hypertension, palpitations, tachyarrhythmias, tachycardia;

CNS: Confusion, convulsions, depression, euphoria, numbness, paraesthesia, syncope, tinnitus, weakness;

Dermatologic: Erythema, itching, rash, urticaria;

Gastrointestinal: Alteration of liver function tests, constipation, diarrhea;

Respiratory: Breathing difficulty, hoarseness, sneezing, wheezing;

Other: Dry mouth, systemic nicotine intoxication.

Reports of myocardial infarction, congestive heart failure, cerebrovascular accident and cardiac arrest, including death have been received. A cause and effect relationship between these reports and the use of NICORETTE[®] Gum has not been established.

Rare reports of miscarriage have been received and a relationship to drug therapy as a contributing factor cannot be excluded.

In addition, rare reports of an apparent severe allergic reaction have been received.

Reduction Studies

The placebo-controlled studies of NICORETTE[®] Gum performed to reduce smoking indicate that smoking concomitantly with use of nicotine gum is well tolerated for up to 12 or 18 months.

In these studies, a total of 1001 subjects were allocated to active treatment and 995 to placebo. The subjects in the active groups reported a total of 1846 adverse events of which 38% were assessed as mild, 35% as moderate and 27% as severe. The 995 subjects in the placebo groups reported a total of 1465 adverse events of which 35% were assessed as mild, 39% as moderate and 26% as severe.

Common Adverse Events

Adverse events in the studies of NICORETTE[®] Gum to reduce smoking did not substantially differ from those seen in smoking cessation studies. The most commonly reported events were headache, influenza-like symptoms, dyspepsia and nausea/vomiting.

Nausea and/or vomiting, hiccups and dyspepsia are mainly related to nicotine gum use. Nausea and/or vomiting were seen in 56/995 (5.6%) and 132/1020 (13%) subjects in the placebo and active treatment groups respectively. Dyspepsia was reported by 49/995 (4.9%) subjects in the placebo group and 87/1020 (8.5%) subjects in the active treatment group. Hiccups were reported by 5/995 (0.5%) subjects in the placebo group compared to 88/1020 (8.6%) in the active treatment group. Throat irritation was reported more frequently in the active group; 49/1020 (4.8%) compared to 7/995 (0.7%) in the placebo group.

Palpitation, a possible sign of systemic nicotine overdose, was reported by less than 1% of subjects who used active treatment, supporting smoking reduction with gum as a safe intervention.

DRUG INTERACTIONS

Overview

The pharmacokinetics of certain concomitant medications may be altered by smoking cessation with or without nicotine replacement. Therefore, the dosage of certain concomitant medications may require adjustment in ex-smokers.

Drug-Drug Interactions

Both smoking and other forms of nicotine can increase circulating cortisol and catecholamines. Therefore, drugs affected by cortisol or catecholamines, such as insulin, may need to be adjusted according to changes in nicotine therapy or smoking status.

Other reported effects of smoking, which do not involve enzyme induction, include reduced diuretic effects of furosemide and decreased cardiac output, and reduced effect on blood pressure with propranolol, which may also relate to the hormonal effects of nicotine. Smoking cessation may reverse these actions.

Table 2 – Established or Potential Drug-Drug Interactions

| Proper name | RefEffect | Clinical comment | |
|---|-----------|--|---|
| acetaminophen caffeine imipramine (and other tricyclic antidepressants) oxazepam (and other benzodiazepines) pentazocine propranolol theophylline | T | Possible mechanism: de-induction of hepatic enzymes on smoking cessation | May require a decrease in dose at cessation of smoking |
| insulin | T | Possible mechanism: increase in subcutaneous insulin absorption with smoking cessation | May require a decrease in dose at cessation of smoking |
| adrenergic antagonists (e.g. prazosin, labetalol) | T | Possible mechanism: decrease in circulating catecholamines with smoking cessation | May require a decrease in dose at cessation of smoking |
| propoxyphene | T | Possible mechanism: "first pass" metabolism decreased | May require a decrease in dose at cessation of smoking |
| adrenergic agonists (e.g. isoproterenol, phenylephrine) | T | Possible mechanism: decrease in circulating catecholamines with smoking cessation | May require an increase in dose at cessation of smoking |

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical

Drug-Food Interactions

Patients should be advised not to consume liquids while chewing NICORETTE[®] Gum as the pH of the oral cavity may be reduced and interfere with absorption of nicotine.

Drug-Lifestyle Interactions

Weight Gain

Weight gain is commonly associated with abstinence from smoking. The mechanism for this is believed to be a combination of the abstinence from the oral habit of cigarette smoking and its replacement by increased intake of food and reduced GI motility due to the absence of the stimulant nicotine. Patients who quit smoking should always be monitored for weight gain.

DOSAGE AND ADMINISTRATION

Dosing Considerations

NICORETTE[®] Gum is an adjunct to smoking cessation (quitting abruptly and quitting gradually) and dosage should be individualized. Although smoking cessation is preferable, NICORETTE[®] Gum can also be used in cases in which a smoker temporarily refrains from smoking; NICORETTE[®] Gum can be used during smoke-free periods, for example in smoke-free areas or in other situations when the patient wishes to avoid smoking.

Each piece should be chewed slowly and intermittently for about 30 minutes. The aim of this chewing is to promote even, slow, buccal absorption of the nicotine released from the buffered gum. Chewing quickly can release the nicotine too rapidly, leading to effects similar to over-smoking, e.g. nausea, hiccups or irritation of the throat.

As the nature of adverse effects experienced by an individual patient will be primarily related to the balance between the degree of nicotine tolerance and the rate and degree of absorption of nicotine from the gum, it is important for the patient to learn to chew the gum slowly and to self-titrate the nicotine dose, in order to minimize side effects.

Recommended Dose and Dosage Adjustment

Quitting Abruptly (Stop-to-Quit)

A patient who is a candidate for this program must desire to quit smoking and should be instructed to stop smoking immediately.

For optimum results, the initial treatment should be based on the patient's level of nicotine dependence, which can be determined by using the Fagerström Nicotine Tolerance Scale (See INDICATIONS AND CLINICAL USE).

If the score is 6 or less, NICORETTE[®] Gum (2 mg) is recommended for use. If the score is 7 or greater or for patients who have cravings with the use of NICORETTE[®] Gum (2 mg), NICORETTE[®] Gum (4 mg) should be used.

Patients should chew one piece of gum whenever they have a craving to smoke.

Most patients require approximately 10 to 12 pieces of gum per day during the first month of treatment. For the first month, about one piece per hour is common for a pack a day smoker. Patients should be instructed not to exceed 20 pieces of NICORETTE[®] Gum per day.

With NICORETTE[®] Gum, as with cigarette smoking, the abrupt cessation of nicotine may result in withdrawal symptoms that may lead to a return to smoking. Therefore, NICORETTE[®] Gum dosing should be gradually reduced. The suggested procedures for a gradual reduction of NICORETTE[®] Gum include, but are not limited to, the following: decrease the total number of pieces of NICORETTE[®] Gum used per day by one or more pieces every 4 to 7 days, substitute one or more pieces of sugarless gum for an equal number of pieces of NICORETTE[®] Gum. The number of pieces of sugarless gum substituted for NICORETTE[®] Gum should be increased every 4 to 7 days.

As guidance, NICORETTE[®] Gum may be chewed every 2 to 4 hours during the second month. During the third month, NICORETTE[®] Gum may be chewed every 4 to 8 hours.

Combination or modification of the above procedures may be adjusted to the individual patient. NICORETTE[®] Gum consumption should be terminated once the patient has successfully broken the smoking habit. This can take up to 6 months in some smokers. It is strongly recommended that NICORETTE[®] Gum pieces be carried by the patient for up to three months following cigarette abstinence in case a sudden overpowering urge to smoke occurs.

Successful abstainers at three months should stop using gum or gradually withdraw from gum usage. Gradual withdrawal from NICORETTE[®] Gum should be initiated after 3 months' usage and completed by 6 months. Patients who chew gum beyond a 3-month period should be considered as possibly using NICORETTE[®] Gum as a substitute source of nicotine for their nicotine dependence. The use of NICORETTE[®] Gum beyond 6 months in the Quitting Abruptly program is not recommended.

NICORETTE[®] Gum dosing may be stopped when usage has been reduced to one or two pieces per day.

Most patients in NICORETTE[®] Gum assisted programs who resumed smoking have done so within 6 months of treatment. If necessary, a separate course of NICORETTE[®] Gum may be prescribed at a later time for patients who continue or resume smoking.

Quitting Gradually (i.e. REDUCE-TO-QUIT[™])

For patients who are not ready or unable to quit abruptly, NICORETTE[®] Gum can be used to facilitate smoking reduction prior to making a quit attempt.

Patients should use NICORETTE[®] Gum whenever they have a craving to smoke in order to prolong smoke-free intervals for as long as possible, with the goal of achieving 50% reduction in daily cigarette consumption between 6 weeks and 4 months of treatment. If such a reduction has not been achieved by 4 months, the patient should be further counselled and/or re-evaluated.

The initial dosage of NICORETTE[®] Gum is individualized. Patients may self-titrate to the level of nicotine they require to reduce the withdrawal symptoms. Patients should be instructed to use a sufficient number of gum pieces each day but not to exceed 20 pieces of NICORETTE[®] Gum.

A reduction of cigarette consumption should be continued until complete cessation can be attempted.

A quit attempt should be made as soon as the patient feels ready but not later than 6 months after the start of treatment. When a patient is ready to make a quit attempt, the instructions outlined under the "Quitting Abruptly" program should be followed.

Regular use of the gum beyond 12 months in the Quitting Gradually program is generally not recommended.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Available in fresh mint, ice mint and fresh fruit flavours.

NICORETTE[®] Gum (2 mg):

Each off-white square of NICORETTE[®] Gum (2 mg) contains: nicotine 2 mg.

The non-medical ingredients for each piece of fresh mint flavoured chewing gum includes: gum base, magnesium oxide, menthol, peppermint oil, sodium bicarbonate and sodium carbonate. Sweetened with xylitol and acesulfame potassium. Contains sodium. Each piece of ice mint flavoured chewing gum also includes: acacia, titanium dioxide and wax.

Each piece of fresh fruit flavoured chewing gum also includes: acacia, flavour, hypromellose, polysorbate, sucralose, titanium dioxide and wax.

NICORETTE[®] Gum (4 mg):

Each yellow square of NICORETTE[®] Gum (4 mg) contains: nicotine 4 mg. The non-medical ingredients for each piece of fresh mint flavoured gum includes: D&C Yellow No. 10, gum base, magnesium oxide, menthol, peppermint oil, and sodium carbonate. Sweetened with xylitol and acesulfame potassium. Contains sodium.

Each piece of ice mint flavoured chewing gum also includes: acacia, titanium dioxide and wax.

Each piece