

Nicorette® Gum

Regular Strength & Extra Strength

Nicotine Chewing Gum

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start to use NICORETTE Gum. This leaflet answers some common questions about NICORETTE Gum and Nicotine Replacement Therapy (also called NRT).

It does not contain all the available information or take the place of professional advice such as talking to your doctor or pharmacist or a counsellor experienced with helping smokers to quit.

All medicines have risks and benefits. You need to weigh the risks of taking NICORETTE Gum against the expected benefits it will have for you.

Use NICORETTE Gum as instructed and follow the advice given in this leaflet.

If you have any concerns about taking this medicine, you can seek the professional advice of your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

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What NICORETTE Gum is used for

NICORETTE Gum helps you to give up smoking by relieving the desire to smoke, as well as some of the unpleasant withdrawal effects which smokers experience when they stop smoking.

Dependence on nicotine can in some cases be transferred from cigarettes to NICORETTE Gum but it is less harmful and easier to break than smoking.

How NICORETTE Gum works

To successfully become a non-smoker it is important to understand how NICORETTE Gum works.

Smokers have both a physical dependence on nicotine (i.e. the body becomes dependent on nicotine) and a psychological (i.e. mental) dependence on the smoking habit itself.

When you give up smoking, your body will miss the effects of nicotine and you will miss the habit of smoking.

NICORETTE Gum helps you to tackle these two sides of the problem separately, instead of all at once.

It is your body's dependence on nicotine which causes withdrawal symptoms when you suddenly stop smoking. Nicotine is an addictive substance.

Symptoms of suddenly stopping smoking may include:

- irritability, frustration or anger
- restlessness
- sleeplessness
- difficulty concentrating
- depression
- increased hunger or weight gain
- craving for cigarettes
- decreased heart rate

NICORETTE Gum is intended to ease such withdrawal symptoms by providing your body with nicotine. This leaves your mind free to concentrate on overcoming your psychological desire to smoke.

NICORETTE Gum releases nicotine into your saliva. The nicotine is absorbed through the lining of your mouth and enters your bloodstream. Any nicotine that is swallowed in saliva is broken down in your stomach. It is therefore wasted. So it is important to chew NICORETTE Gum slowly so that the nicotine is released a little at a time and absorbed through the lining of the mouth.

This nicotine is sufficient to decrease the cravings for smoking. Unlike cigarettes NICORETTE Gum does not contain harmful tar and carbon monoxide.

NICORETTE Gum helps you give up smoking by relieving nicotine craving, but you will only be successful in becoming a non-smoker if you are determined to quit.

You will need to plan your stop-smoking programme.

You will also need the support of others, your family, your friends, your pharmacist, family doctor or practice nurse or any one of a number of "quit smoking" organisations.

Do not be afraid to seek support or advice.

For the NICORETTE programme to be effective you must not smoke at all while using NICORETTE Gum.

Before using NICORETTE Gum

*When you must not use
NICORETTE Gum*

Do not use NICORETTE Gum if:

- **You are pregnant or intend to become pregnant**

There is medical evidence that nicotine in any form may be harmful to an unborn child. If you are pregnant or intend to become pregnant, you should try to quit smoking without using nicotine products. However, if this is not possible, your doctor may advise you to use NICORETTE Gum.

- **You are breastfeeding or intend to breastfeed**

Nicotine passes freely into breast milk and can affect the health of the baby. If you are breastfeeding or intend to breastfeed, you should try to quit smoking without using nicotine products. However, if this is not possible, your doctor may advise you to use NICORETTE Gum.

- **You have heart disease such as palpitations (fast or irregular heart beats) or angina**
- **You have had a recent heart attack or a stroke**
- **You are a non-smoker, or only smoke occasionally**
- **You are under 18 years of age**

There is not enough information about the use of NICORETTE Gum in children.

- **You are allergic to nicotine or to any of the ingredients listed under the Product Description at the end of this leaflet.**

You should not use NICORETTE Gum if the expiry date printed on the carton has passed or the packaging is torn or shows signs of tampering.

If you are uncertain whether you can use NICORETTE Gum, speak to your doctor or pharmacist.

Do not give NICORETTE Gum to anyone else to use without professional advice from a doctor or pharmacist.

*Before you start to use
NICORETTE Gum*

If you have any of the following, you should ask for your doctor's or pharmacist's advice before using NICORETTE Gum.

These medical conditions may need consideration by or discussion with your doctor or pharmacist. You and your doctor or pharmacist can then weigh up the risk of using NICORETTE Gum against the benefits you will get if you stop smoking.

The medical conditions include:

- any type of heart disease, including angina, heart failure
- high blood pressure
- any blood circulation disorder
- kidney disease
- stomach ulcer or pain
- Hyperthyroidism (a disorder of the thyroid gland)
- Diabetes that is controlled with insulin
- Pheochromocytoma (a tumour of the adrenal gland)
- liver disorder.

If you have dentures, dental caps or partial bridges

NICORETTE Gum may stick to your dentures, dental caps or partial bridges and therefore may cause damage to your dental work. It is important that your dental work is kept clean. You should stop chewing NICORETTE Gum if it is sticking to your dental work and discuss further use of NICORETTE Gum with your doctor and dentist.

Taking other medicines

If you are taking any other medicines, including medicines that you buy without a prescription, in a pharmacy, supermarket or health food shop, the way these medicines work may be affected once you stop smoking

These medicines may include:

- Theophylline, a medicine for asthma

- Imipramine, Clomipramine and Fluvoxamine, these are medicines for depression
- Pentazocine, a medicine for pain relief
- Clozapine, Olanzapine and Tachrine, these are medicines for mental conditions
- Flecainide, a medicine for irregular and/or rapid heartbeat
- caffeine.

Tell your doctor or pharmacist if you are taking any of these medicines before you start to use NICORETTE Gum.

Using NICORETTE Gum

What is the proper chewing method?

Do not chew NICORETTE Gum when eating or drinking.

This causes excessive swallowing of nicotine, reducing the effectiveness of NICORETTE Gum. Do not drink acidic beverages, such as coffee or soft drinks, for 15 minutes before chewing as they can interfere with the absorption of nicotine.

To get the full effect from NICORETTE Gum these steps should be followed carefully:

1. **Place one piece of NICORETTE Gum in your mouth and chew it slowly until you feel a slight tingling sensation.**
2. **When you feel the tingling (usually after about 10 chews), place the piece of gum under your tongue or between your cheek and gums until the tingling has gone. This will take about one minute.**
3. **When the tingling has gone, continue to chew the gum slowly until the tingling returns. Then again place the gum under your tongue or between your cheek and gums.**

4. **Chew each piece of NICORETTE Gum in this way until you no longer experience the tingling sensation. Each piece of gum will usually last about 30 minutes.**
5. **Dispose of the chewed pieces of gum neatly, e.g., return to the bubble pack.**

Proper chewing is important

NICORETTE Gum releases nicotine into your saliva. This nicotine is absorbed through the lining of your mouth and enters your bloodstream. Any nicotine that is swallowed in saliva is broken down in your stomach. It is therefore wasted.

So it is important to chew NICORETTE Gum slowly so that the nicotine is released a little at a time and absorbed through the lining of the mouth. If NICORETTE Gum is chewed too quickly or for too long, a lot of saliva is produced and swallowed which reduces NICORETTE's ability to work effectively. Too much chewing may also produce an unpleasant strong taste, which is a useful sign that you should slow down or stop chewing. Chewing too quickly may at first irritate the throat or cause hiccups or make you feel sick.

So remember that if the taste is too strong you are chewing too fast!

Which strength of NICORETTE Gum should I use?

You should discuss which strength of NICORETTE Gum you should use with your pharmacist. NICORETTE Gum is available from a pharmacy in 2 milligram (mg) and 4 mg strengths.

Usually, the 4 mg strength is recommended if you smoke 20 or more cigarettes in a day or are a smoker who has not been able to quit smoking using the 2 mg strength. Otherwise, you should use the 2 mg strength.

How much NICORETTE Gum should I use?

The amount of NICORETTE Gum you chew each day depends on your former smoking habits. Usually, it is recommended that a piece of NICORETTE Gum should be used when the urge to smoke is felt. Because nicotine is released from NICORETTE Gum at a slower rate than from a cigarette, it is important that you do not try to delay chewing in the hope that the urge to smoke will go away. NICORETTE Gum needs extra time to work and be effective.

The average dose tends to be in the range of 8-12 pieces of the 2 mg strength a day or 4-6 pieces of 4 mg gum a day.

It is recommended that you do not chew more than 20 pieces of 2 mg gum or 10 pieces of 4 mg gum in one day.

When to start using NICORETTE Gum

Set a Stop Smoking Day so that you can plan to be ready . This allows you to:

- Pick the right day - set a quit date that is likely to be stress free.
- Quit with a friend- you can help each other stick to your plan.
- Remove any temptation - make home and work cigarette-free zones.
- Take one day at a time - every day without a cigarette makes you a winner.
- Keep yourself busy - do something you enjoy.
- Think cash, not ash - your money will no longer be going up in smoke.
- Avoid putting on weight - start a gentle exercise regimen.
- If at first you don't succeed don't give up. Successful quitters keep trying.

When your Stop Smoking Day arrives, stop smoking completely on that day and begin your NICORETTE treatment.

When to stop using NICORETTE Gum

It is recommended that NICORETTE Gum be used for 12 weeks to help you get over your psychological desire to smoke. After 12 weeks, you should gradually reduce the number of pieces of NICORETTE Gum chewed each day. It should take another 4 weeks to step down to using 1 to 2 pieces per day. Don't be discouraged by this, it is all part of the quitting process.

When you reach this stage you can call yourself an ex-smoker, but there is still the chance that you may lapse back to your smoking habit, so always carry some NICORETTE Gum just in case you feel an urge to smoke.

The use of NICORETTE Gum beyond one year is not recommended.

If you take too much (overdose)

Stop smoking completely when you start using NICORETTE Gum. Symptoms of nicotine overdose can occur if you smoke at the same time as you use NICORETTE Gum or if many pieces of NICORETTE Gum are chewed at the same time or rapidly one after the other.

Signs of overdose or poisoning include:

- nausea and vomiting
- salivating
- diarrhoea
- abdominal pain
- sweating
- headache
- dizziness
- disturbed hearing
- weakness, faintness and fatigue
- breathing difficulties
- loss of consciousness

- weak, rapid or irregular pulse

Keep NICORETTE Gum out of the reach of children. Seek medical advice immediately if a young child chews, swallows or sucks any quantity of NICORETTE Gum.

Children have a greater risk of poisoning from NICORETTE Gum if accidentally chewed, swallowed or sucked. **Young children can be poisoned by small amounts of nicotine.**

In the event of yourself or another adult chewing or swallowing large quantities of NICORETTE Gum, seek medical advice.

Immediately telephone your doctor or Poisons Information Centre for advice (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital.

Side effects

Nicotine like all other medicines may cause unwanted side-effects in some people.

Seek professional advice from your doctor or pharmacist as soon as possible if you do not feel well while you are using NICORETTE Gum.

Do not smoke or use NICORETTE Gum or other nicotine medicines and see your doctor as soon as possible if you get:

- Chest pain or
- bad indigestion or
- an irregular (uneven) heart beat

Most of the undesirable effects reported by users of NICORETTE Gum occur during the first weeks after beginning treatment and may be due to chewing incorrectly or to the effects of nicotine. Some are minor and temporary but others may need medical attention. The most common side effects are:

- headache
- nausea and vomiting
- indigestion
- hiccups
- sore mouth or throat

- jaw muscle ache
- skin irritation, itching or redness

These may diminish during the first weeks of using NICORETTE Gum.

Seek professional advice if you are not sure.

Some effects, such as dizziness, headache, sleeplessness and mouth ulcer may be withdrawal symptoms due to low nicotine levels.

If any of these effects do not go away, or you have any other undesirable effects during use, tell your pharmacist or doctor
REMEMBER - that NICORETTE Gum is not intended as an alternative to smoking and that your aim is to overcome your need for nicotine by the end of the treatment period.

After using NICORETTE Gum

Storage

The expiry date of NICORETTE Gum is on the label of the carton and on the foil of the bubble pack. Do not use NICORETTE Gum if the expiry date has passed. Leave all pieces in the bubble pack until immediately before use.

Store NICORETTE Gum in a cool place where the temperature stays below 25°C. Exposure to temperatures greater than 25°C (e.g. if carried in a shirt pocket or stored in a car glove box for long periods) may cause deterioration of the Gum.

KEEP NICORETTE GUM OUT OF REACH OF CHILDREN.

Disposal

When NICORETTE Gum is no longer needed, dispose of it carefully, where children or animals cannot get it.

Product Description

What NICORETTE Gum looks like

There are four flavours of NICORETTE Gum:

NICORETTE Classic
NICORETTE Mint
NICORETTE Freshmint and
NICORETTE Citrus.

NICORETTE Gum comes as square-shaped pieces of chewing gum in two strengths, 2 milligrams (mg) and 4 mg.

The 2 mg strengths of Nicorette Classic, Mint and Citrus are a beige colour.

The 4 mg strengths of Nicorette Classic, Mint and Citrus are a yellow colour.

The 2 mg strength of Nicorette Freshmint has a white coating.

The 4mg strength of Nicorette Freshmint has a cream coloured coating.

The 2 mg strength is available in packs of 30 and 105 pieces and the 4 mg strength is available in packs of 30 and 105 pieces.

Identification

NICORETTE Gum can be identified by an Australian Register Number which is found on the carton:

NICORETTE Classic:

AUST R 12515 for the 2mg strength
AUST R 12516 for the 4mg strength

NICORETTE Mint:

AUST R 45840 for the 2mg strength
AUST R 45839 for the 4mg strength

NICORETTE Freshmint:

AUST R 115009 for the 2mg strength
AUST R 115010 for the 4mg strength

NICORETTE Citrus:

AUST R 62298 for the 2mg strength
AUST R 62189 for the 4mg strength

Ingredients

The active ingredient in NICORETTE Gum is nicotine polacrilex.

NICORETTE CLASSIC Gum:

Other ingredients in both strengths of NICORETTE CLASSIC Gum are chewing gum base, sodium carbonate anhydrous, glycerol, sorbitol powder, sorbitol solution, haverstroo flavour ZD49284, and flavour for smoker 846422.

An ingredient found only in 2 mg Nicorette Classic Gum is sodium bicarbonate.

An ingredient found only in 4 mg NICORETTE CLASSIC Gum is quinoline yellow.

NICORETTE MINT Gum:

Other ingredients in both strengths of NICORETTE MINT Gum are chewing gum base, xylitol, sodium carbonate anhydrous, magnesium oxide, menthol and peppermint oil.

An ingredient found only in 2 mg NICORETTE MINT Gum is sodium bicarbonate.

An ingredient found only in 4 mg NICORETTE MINT Gum is quinoline yellow.

NICORETTE Freshmint Gum:

Other ingredients in both strengths of NICORETTE FRESHMINT Gum are chewing gum base, xylitol, peppermint oil, sodium carbonate anhydrous, acesulfame potassium, levomenthol, magnesium oxide light, acacia, titanium dioxide, and carnauba wax.

An ingredient found only in 2mg NICORETTE FRESHMINT Gum is sodium bicarbonate.

An ingredient found only in 4mg NICORETTE FRESHMINT Gum is quinoline yellow.

NICORETTE CITRUS Gum:

Other ingredients in both strengths are chewing gum base, sodium carbonate anhydrous, xylitol, magnesium oxide light and blood orange flavour.

An ingredient found only in 2 mg NICORETTE CITRUS Gum is sodium bicarbonate. An ingredient found only in 4 mg NICORETTE CITRUS Gum is quinoline yellow.

Where to go for further information

If you need further information on NICORETTE Gum call 1300 362 486.

Manufacturer and Supplier

NICORETTE Gum is supplied in Australia by:

Pfizer Consumer Healthcare
32 Cawarra Road, Caringbah
NSW 2229, Australia

www.nicorette.com.au

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