

Nicotrol[®] gum and Nicotrol[®] gum mint

nicotine

2 mg, 4 mg, chewing gum

What is in this leaflet

This leaflet answers some common questions about Nicotrol Gum. It does not contain all the available information or take the place of professional advice such as talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

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

What Nicotrol Gum is used for

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

Nicotrol Gum is also used to help smokers who need to temporarily stop smoking e.g. on long air flights. Nicotrol Gum can also help reduce the amount of cigarettes smoked in smokers who are unable or unwilling to quit.

How Nicotrol Gum works

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

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

Nicotrol 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 may include irritability, restlessness, depression, weight gain, and craving for cigarettes.

Nicotrol 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.

Before using Nicotrol Gum

When you must not use the Nicotrol Gum

Do not use Nicotrol 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. Therefore it is recommended that you do not use Nicotrol if you are pregnant or intend to become pregnant, unless you are unable to stop smoking without nicotine replacement. Talk to your doctor before using Nicotrol Gum during pregnancy.
- **You are breast-feeding or intend to breast-feed**
Nicotine passes freely into breast milk, and can affect the health of the baby. Therefore it is recommended that you do not use Nicotrol Gum if you are breast-feeding or intend to breast-feed.
- **You have had a recent heart attack or stroke**
- **You have heart disease such as palpitations (fast or irregular heart beats) or uncontrolled angina (chest pain)**
- **You are a non-smoker**
- **You are under 18 years old**
There is not enough information about the use of Nicotrol Gum in children.
- **You are allergic to nicotine or sensitive to any components of the chewing gum.**

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

Do not give Nicotrol Gum to anyone else to use as it is recommended that they seek professional advice prior to starting treatment.

Before you start to use Nicotrol Gum

If you have had any of the following, you should ask for your doctor or pharmacist's advice before using Nicotrol 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 Nicotrol Gum against the benefits you will get if you stop smoking.

The medical conditions include:

- Angina (chest pain) or any other problem with your heart or blood vessels such as pain in one or more legs when you walk
- High blood pressure

- Previous stroke
- Kidney disease
- Liver disease
- Stomach ulcer or pain
- Hyperthyroidism (a disorder of the thyroid gland)
- Pheochromocytoma (a tumour of the adrenal gland)
- Diabetes.

If you have dentures, dental caps or partial bridges

Nicotrol 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 Nicotrol Gum if it is sticking to your dental work and discuss further use of Nicotrol 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 (asthma medication)
- Insulin
- Imipramine (antidepressant)
- Pentazocine (pain medication).

You may wish to seek professional advice from your doctor or a pharmacist before you start to use Nicotrol Gum.

Using Nicotrol Gum

What is the proper chewing method?

Do not chew Nicotrol Gum when eating or drinking.

This causes excessive swallowing of nicotine, reducing the effectiveness of Nicotrol. 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 Nicotrol Gum these steps should be followed carefully:

- 1 Place one piece of Nicotrol 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 Nicotrol in this way until you no longer experience the tingling sensation. Each piece of Nicotrol will usually last about 30 minutes.
- 5 Dispose of the chewed pieces of gum neatly, e.g. return to the bubble pack.

Why is proper chewing so important?

Nicotrol 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 Nicotrol Gum slowly so that the nicotine is released a little at a time and absorbed through the lining of the mouth.

If Nicotrol Gum is chewed too quickly or for too long, a lot of saliva is produced and swallowed which reduces Nicotrol'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 Nicotrol Gum should I use?

Nicotrol Gum is available in 2 milligram (mg) and 4 mg strengths. Usually, the 4 mg strength is recommended if you smoke 20 cigarettes or more 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 Nicotrol Gum should I use?

The amount of Nicotrol Gum you chew each day depends on your former smoking habits. Usually, it is recommended that a piece of

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Nicotrol should be used when the urge to smoke is felt. About 8 to 12 chewing gums, of either the 2 mg or 4 mg strength, each day will be adequate. No more than 24 gums should be used daily.

How long should I continue to use Nicotrol Gum

To quit smoking:

It is important that you use Nicotrol Gum for long enough to help overcome your dependence on cigarettes. Normally this period will be at least 3 months. Then you can start to slowly wean yourself from using the gum. When you are only using 1 to 2 chewing gums each day, then you can stop the treatment.

Temporary abstinence:

Nicotrol chewing gum should be used during smoke-free periods, for example in smoke free areas or in situations when you wish to avoid smoking.

Smoking reduction:

Use Nicotrol Gum between smoking episodes to prolong smoke-free intervals and with the intention to reduce your smoking as much as possible. If after 6 weeks you have not reduced the number of cigarettes smoked each day, then you should seek professional advice.

You should try to quit smoking as soon as you feel ready, but no later than 6 months after starting your treatment. If 9 months has passed since starting Nicotrol Gum and you have still not been able to make a serious attempt at quitting smoking, then seek professional advice.

Regular use of the gum after 12 months is not recommended. Some ex-smokers may need longer treatment to avoid returning to smoking.

How to combine use of nicotine patch and Nicotrol Gum

Normally nicotine patch or Nicotrol Gum alone would provide enough nicotine to help most people control their craving for cigarettes. However, some people may find that even though they are using nicotine replacement therapy (NRT) they still have intense or frequent cravings they find difficult to cope with. If you are one of these people you may benefit from combining nicotine patch use with Nicotrol 2 mg Gum.

Each morning apply a nicotine 15 mg/16 hour patch to an intact area of skin. The nicotine patch should be removed before going to bed. After applying the nicotine patch use Nicotrol 2 mg Gum whenever a craving occurs.

For best results try to chew at least 4 pieces of Nicotrol Gum every day. Most people will use 5-6 pieces. Do not use more than 24 pieces of gum.

The combination of nicotine patch and Nicotrol Gum should be used in this way for 6-12 weeks. After this time if required you can wean yourself off NRT by either:

1. Use the nicotine 10 mg/16 hour patch for 3-6 weeks and then use the nicotine 5 mg/16 hour patch for 3-6 weeks while using the same number of pieces of Nicotrol Gum in a day that you have routinely used. Then when a patch is no longer needed, gradually reduce the number of pieces of gum until you no longer need them. OR
2. Stop use of the nicotine 15 mg/16 hour patch and then gradually reduce the number of pieces of Nicotrol 2 mg Gum that are used until you no longer need them.

If you use too much (overdose) or in accidental poisoning

Overdose of nicotine can occur if nicotine is used excessively, either from chewing too many pieces of Nicotrol Gum at the same time or rapidly one after the other, and/or smoking.

Symptoms of overdose or poisoning include:

- Nausea and vomiting
- Salivating
- Diarrhoea
- Abdominal pain
- Cold sweats
- Weakness
- Disturbed hearing
- Headache
- Breathing difficulties
- Weak, rapid or irregular pulse
- Loss of consciousness.

Children have a greater risk of poisoning from nicotine, therefore it is important to keep Nicotrol Gum out of reach of children.

In the event of yourself or someone else showing symptoms seek medical advice. **Immediately telephone your doctor or the National Poisons Information Centre (telephone 03 474 7000) for advice, 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 Nicotrol Gum. Most of the undesirable effects reported by users of Nicotrol occur during the first weeks after beginning treatment and are most likely due to chewing incorrectly or to the effects of nicotine. Some are minor and temporary but others may need medical attention.

You may notice the following:

- Headache
- Nausea and/or vomiting
- Hiccups
- Sore mouth or throat
- Jaw-muscle ache
- Redness of the skin
- Hives
- Mouth ulcers.

Some effects, such as dizziness, headache and sleeplessness 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 doctor or pharmacist.

After using Nicotrol Gum

Storage

The expiry date of the Nicotrol Gum is on the label of the carton and on the foil of the blister pack. Do not use Nicotrol Gum if the expiry date has passed.

Leave all pieces in the blister pack until immediately before use.

Store Nicotrol Gum below 25 °C. Storage in a car in hot weather may cause deterioration of the Gum.

KEEP NICOTROL GUM OUT OF REACH OF CHILDREN.

(See section on 'If you use too much (overdose) or in accidental poisoning').

Disposal

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

Product description

What Nicotrol Gum looks like

As well as the Nicotrol Gum there is an additional mint flavour: Nicotrol Gum Mint.

The 2 mg strength is a beige colour. The 4 mg strength is a yellow colour.

Nicotrol Gum and Nicotrol Gum Mint are available in packs of 105 pieces.

Nicotrol Gum is a General Sales Medicine.

Ingredients

The active ingredient in Nicotrol Gum is nicotine-resin complex.

Nicotrol Gum:

Other ingredients in both strengths of Nicotrol Gum are chewing gum base, sorbitol powder, sorbitol 70%, flavour for smoker, haverstroo flavour, sodium carbonate anhydrous and glycerol 85%.

Nicotrol Gum Mint:

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

An ingredient found only in the 2 mg Nicotrol Gum and Nicotrol Gum Mint is sodium hydrogen carbonate.

An ingredient found only in the 4 mg Nicotrol Gum and Nicotrol Gum Mint is quinoline yellow Al-lake E 104.

Supplier

Nicotrol Gum is supplied in New Zealand by:

Pharmacia
PO Box 11-282
Ellerslie
Auckland

For medical enquiries call (09) 5804300

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