November 2021

Please note that there are currently 2 leaflets available for the Nicorette 2mg Gum licence (PL 15513/0169).

It is the same product licence number for both leaflets i.e PL 15513/0169.

The information contained within each leaflet is identical apart from the manufacturer details into section 6.

1. PIL 1 (pages 2-3) - The manufacturer is McNeil AB, Helsingborg, Sweden.

   or

2. PIL 2 (pages 4-5) - The manufacturer is McNeil Products Ltd, 50 - 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

This is a combined pdf of both leaflets.

Both leaflets are marketed. However, there will only be one of the leaflet formats in each carton.
Nicotine replacement therapy can help relieve nicotine withdrawal symptoms such as irritability, low mood, anxiety, restlessness and cravings when used in place of cigarettes.

NRT may benefit smokers who want to quit, by helping to control weight gain that may be experienced when trying to stop smoking.

Use of NRT is safer than smoking tobacco but as soon as you are ready, you should aim to stop smoking completely.

2 Before using this medicine

Do not use nicotine- gum do:

1. If you were a child under 12 years of age.
2. If you have an allergy to nicotine or any of the other ingredients.

Talk to your doctor, nurse or pharmacist...

- If you are pregnant or breast-feeding – you may be able to use nicotine replacement therapy (NRT) to help you stop smoking but you should try to give up without it. See “If you are pregnant or breast-feeding” section.
- If you are in hospital because of heart disease (including heart attacks, disorders of heart rate or rhythm, angina, high blood pressure or stroke). In other heart conditions not requiring you to be in hospital, using NRT is better than continuing to smoke.
- If you have a stomach ulcer, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus (passage between the mouth and stomach).
- If you have ever had kidney disease.
- If you have an overactive thyroid gland (a tumour of the adrenal gland that can affect blood pressure) – your doctor will have told you not to take NRT.
- If you have diabetes – monitor your blood sugar levels more often when starting to use NICTOR® Gum as you may find your results or medication requirements alter.

Nicotine replacement therapy can help relieve nicotine withdrawal symptoms such as irritability, low mood, anxiety, restlessness and cravings when used in place of cigarettes.

If you are taking other medicines such as theophylline, clonazepam or zopiclone. Smoking stopping or cutting down may require the doses of these medicines to be adjusted.

If you have ever experienced seizures (fits).

If any of these apply, talk to your doctor, nurse or pharmacist.

Some of the ingredients can cause problems.

- The chewing gum base contains butylated hydroxy toluene (E321), an anti-oxidant. May cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and skin.
- Each 2mg gum contains 100-25 mg sorbitol. Each 4mg gum contains 178.97 mg sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or review this medicine.
- This medicine contains 0.616 mg of alcohol (ethanol) in each gum. The small amount of alcohol in this medicine will not have any noticeable effects.
- The medicine contains less than 1 mlm sodium (23 mg) in each chewing gum, that is to say essentially sodium-free.

If you are pregnant or breast-feeding

If you are pregnant:
1. Firstly, you should try to give up smoking without NRT.
2. Secondly, if you can’t manage this you are best to use NRT products that are taken intermittently (not patches), however you should talk to your doctor, nurse or pharmacist for advice.

Breast-feed just before you use NICORETTE® Gum to ensure that the baby gets the smallest amount of nicotine possible.

If you do not need to use NRT to help you quit, the amount of nicotine that the baby may receive is considerably smaller and less harmful than the second-hand smoke they would receive if you smoked. Tobacco smoke produces breathing and other problems in babies and children.

How and when to use this medicine

How to chew NICORETTE® gum

The following sections contain the dosage information for NICORETTE® Gum. This shows the number of gums you should be using, when you should take them, how you should be using NRT and passes into your body through the lining of your mouth. The nicotine released from the gum adheres to the unabsorbed unpleasant withdrawal symptoms. It will also help to stop the craving to smoke, but NICORETTE® Gum will not give you the “buzz” you get from smoking a cigarette.

Benefits you can get from using NRT instead of smoking

For the best effect, make sure you chew NICORETTE® Gum correctly. See “How to chew NICORETTE® Gum – the NICORETTE® Chewing Technique”. The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT. It is the toxins in cigarette smoke such as tar, lead, cyanide and carbon monoxide related diseases and death, not the nicotine.

You may think that smoking helps relieve feelings of anxiety and stress, but it does not deal with the cause of the stress and leads to a number of serious diseases. In addition, the feeling of relaxation after smoking is temporary, with withdrawal symptoms and cravings soon returning.

You don’t want to smoke and aren’t used to others e.g. children or family.

- Smoke free areas e.g. Pub, work, public transport & aeroplanes.

It may also help increase your motivation to quit. When making a quit attempt a behavioural support programme will increase your chances of success.

If you smoke 20 or fewer cigarettes a day, the 2 mg nicotine gum will help reduce your cravings. If you smoke more than 20 cigarettes a day, 4 mg nicotine gum may be more appropriate.

What does nicorette- gum do?”

When you stop smoking, or cut down the number of cigarettes you smoke, your body releases the nicotine that you have been absorbing. This may experience unpleasant withdrawal symptoms such as irritability, low mood, anxiety, restlessness and cravings when used in place of cigarettes.

NRT may benefit smokers who want to quit, by helping to control weight gain that may be experienced when trying to stop smoking.

Use of NRT is safer than smoking tobacco but as soon as you are ready, you should aim to stop smoking completely.

1 The medicine is for NICORETTE® Gum is a nicotine replacement therapy (NRT). It is used to reduce and/or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking, or when cutting down the number of cigarettes you smoke.

NICORETTE® Gum can also be used when you are pregnant or breast-feeding to help you stop smoking, as the risks to your baby are far less than if you continue to smoke. For more information, see “if you are pregnant or breast-feeding” section.

Ideally you should always aim to stop smoking. You can use NICORETTE® Gum to achieve this by using it to completely replace all your cigarettes. However NICORETTE® Gum can also be used in other ways.

- If you feel unable to stop smoking completely, or wish to replace a certain cigarette and therefore can help you to cut down the number of cigarettes you smoke.
- In those times when you can’t or do want to smoke.

Number of cigarettes Dose of Gums

<table>
<thead>
<tr>
<th>Number of cigarettes you smoke per day</th>
<th>Dose of Gums</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 10 cigarettes</td>
<td>2 mg nicotine gum</td>
</tr>
<tr>
<td>10-20 cigarettes</td>
<td>4 mg nicotine gum</td>
</tr>
<tr>
<td>21-50 cigarettes</td>
<td>4 mg nicotine gum</td>
</tr>
<tr>
<td>More than 50 cigarettes</td>
<td>4 mg nicotine gum</td>
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</tbody>
</table>

How to chew NICORETTE® gum – the NICORETTE® Chewing Technique

For more information, see “how to chew NICORETTE® Gum – the NICORETTE® Chewing Technique”.

Keep chewing like this for about half an hour. After this time the gum will have lost its strength and you should dispose of it correctly.
Possible side-effects
Like all medicines, NICORETTE® Gum can have side-effects. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Effects related to stopping smoking (nicotine withdrawal)
You may experience unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. You may also experience these effects if you under use NICORETTE® Gum before you are ready to reduce your nicotine intake.

These effects include:
- irritability or aggression
- feeling low
- anxiety
- moodiness
- poor concentration
- increased appetite or weight gain
- trouble to concentrate
- difficulty in sleeping or sleep disturbance
- loss of taste
- dizziness, light-headedness, blurry vision, nausea
- cough
- constipation
- vomiting of food
- mouth ulcers
- swelling of the nasal passages and back of the throat
- effects of too much nicotine
You may also get these effects if you are not used to inhaling tobacco smoke.

These effects include:
- feeling faint
- feeling sick (nausea)
- headache
- Nick in the ear (due to excessive swallowing of nicotine)

Side-effects of NICORETTE® gum
NICORETTE® Gum can sometimes stick to dentures and in rare cases damage them. If you do not get any of these effects contact a doctor or your nearest hospital Accident and Emergency department immediately. Take this leaflet and the pack with you.

NicoPhen Ingestion by a child may result in severe poisoning.

5 Storing and disposal
Keep NICORETTE® Gum out of sight and reach of children and animals. Nicotine in high doses can be very dangerous and sometimes fatal taken by children.

Do not store NICORETTE® Gum above 25°C.

Do not use the gum after the “Use before” date on the box or blister strip.

Disperse of NICORETTE® Gum sensibly.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines that are no longer needed. These measures will help to protect the environment.

6 Further information
What's in this medicine?
The active ingredient in NICORETTE® 2 mg Gum is 2 mg Nicotine. The active ingredient in NICORETTE® 4 mg Gum is 4 mg Nicotine.

Other ingredients are: Chewin gum base, sorbitol, sodium carionate, flavourings (contains anise), pollicin, glycerol and bic.

The chewing gum base contains E475 (hydroxy stearate (E475), an anti-oxidant).

The 3 mg gum also contains soybean lecithin.

The 4 mg gum also contains quinoline yellow (E104) (yellow colour).

The gum does not contain sugar (sucrose) or animal products.

What the medicine looks like
The gums are blister packed in sheets of 6 or 15, supplied in packs of 6, 15, 30, 75, 105, 165 and 210 pieces. Not all pack sizes may be marketed.

Who makes NICORETTE® gum?
The Product Licence holder is MCC Products Limited, 50-100 Holmfield Park Way, High Wycombe, Buckinghamshire, HP12 4EL, UK.
The manufacturer is McNeil AB, Helsingborg, Sweden.

This leaflet was revised in January 2021.

McNeil Product Limited 2021 ©
nicorette
2 mg and 4 mg Gum
Nicotine chewing gum
What you should know about nicorette
2 mg Gum
(4 mg nicotine chewing gum)
2 mg nicotine gum
(8 mg nicotine chewing gum)
Please read this leaflet carefully before you start using this medicine. It provides useful information on how to use it safely and effectively. If you think you are having side effects, see your doctor or pharmacist.

1 What is the medicine for?
Nicorette® Gum is a nicotine replacement therapy (NRT) used to help stop smoking. It contains nicotine which is the active ingredient in cigarettes.

2 How do you use this medicine?
Before using this medicine
- If you are pregnant or breast-feeding, see your doctor.
- If you have a stomach ulcer, see a doctor.
- If you have liver or kidney disease, see your doctor.
- If you have an overactive thyroid gland, see your doctor.
- If you have grromocytoma (a tumour of the adrenal gland), see your doctor.
- If you have any other medical conditions, see your doctor.
- If you are taking any other medicines or herbal products, see your doctor.

3 Benefits you can get from using NRT instead of cigarettes
- You may experience unpleasant feelings in your mouth. It will also help you to stop smoking.
- Nicotine replacement therapy can help reduce nicotine withdrawn symptoms such as irritability, low mood, anxiety, concentration difficulties and craving, which can be a reason to stop smoking.
- The benefits of stopping smoking far outweigh any risk of using nicotine from NICORETTE® Gum.

4 Talk to your doctor, nurse or pharmacist...
- If you are using NICORETTE® Gum correctly, this leaflet will help you.
- If you are using NICORETTE® Gum incorrectly, this leaflet will not help you.

5 What does NICORETTE® Gum do?
When you stop smoking, or cut down the number of cigarettes you smoke, your body makes the nicotine that your body feels and craves. It also helps to stop the smoking from nicotine. NICORETTE® Gum will help you to take the “flap” you get from smoking a cigarette.

6 Nicorette® gum can be used when you are pregnant or breast-feeding to help you stop smoking. As with other medicines, NICORETTE® Gum has been shown to be safe when used in this way.

7 Beware of stopping smoking for anything other than smoking Withdrawal symptoms When you stop smoking or cut down the number of cigarettes you smoke, your body stops making nicotine. NICORETTE® Gum releases a small amount of nicotine into your mouth. It is absorbed into your bloodstream and helps you to stop smoking.

8 How to use NICORETTE® Gum
- If you are using NICORETTE® Gum correctly, this leaflet will help you.
- If you are using NICORETTE® Gum incorrectly, this leaflet will not help you.

9 Talk to your doctor, nurse or pharmacist...
- If you are using NICORETTE® Gum correctly, this leaflet will help you.
- If you are using NICORETTE® Gum incorrectly, this leaflet will not help you.

10 Use NICORETTE® Gum to help you stop the smoking habit. NICORETTE® Gum can help you stop smoking at any time, in any situation that might previously have led to a cigarette being smoked.

11 How to use NICORETTE® Gum
- If you are using NICORETTE® Gum correctly, this leaflet will help you.
- If you are using NICORETTE® Gum incorrectly, this leaflet will not help you.

12 Beware of stopping smoking for anything other than smoking withdraw.

13 Nicotine replacement therapy can help reduce nicotine withdraw symptoms such as irritability, low mood, anxiety, concentration difficulties and craving, which can be a reason to stop smoking.

14 The benefits of stopping smoking far outweigh any risk of using nicotine from NICORETTE® Gum.
**Possible side-effects**

Like all medicines, NICORETTE® Gums can have side-effects. The range of the effects are rare or common. They can also occur when someone is not smoking by smoking.

**Effects related to stopping smoking**

If you notice any of the following side-effects, you may experience unusual effects because of stopping smoking. You have reported the number of effects to the contractor. You may also experience any of the following side-effects. If you continue to use NICORETTE® Gums before you are ready to reduce your nicotine intake.

**These effects include:**

- Headache
- Rash
- Dizziness
- Swollen lymph nodes
- Drowsiness
- Swollen, red, sore tongue
- Mouth ulcers
- Vomiting
- Diarrhoea
- Convulsions
- Unusual tiredness
- Rash, hives (urticaria)
- Inner constriction of the small airways of the lung
- Stomach pain or indigestion
- Jaw-muscle ache
- Lack of concentration
- Jaw pain or swelling
- Fever
- Mouth pain or swelling
- General feeling of discomfort or being unwell or out of control

**Rare side-effects:**

Rare side-effects are those in which over 1,000 people are affected or difficult in swallowing.

**Other side-effects can include:**

- Inner constriction of the small airways of the lung
- Nausea
- Rash, hives (urticaria)
- Inner constriction of the small airways of the lung
- Diarrhoea
- Fever
- Weakness
- Inner constriction of the small airways of the lung
- Rash
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- Fever
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- Fever
- Weakness
- Inner constriction of the small airways of the lung
- Rash

Further information

**What’s in this medicine?**

NICORETTE® Gums in the mouth contain: 7 mg Gum in 2 mg nicotine. Medicines not replace smoking.

**Other ingredients are:**

- Nicotine (in NICORETTE® Gums in 3 mg Gum is 4 mg nicotine).
- Other ingredients are: Chewing gum base, sweetener, sodium saccharin, magnesium stearate, yellow dye (E100), potato starch and white sugar.

The chewing gum contains butylated hydroxytoluene (BHT), as an anti-oxidant. The 2 mg gum also contains quinoline yellow (E104) yellow dye.

This gum does not contain sugar (sucrose) in animal products.

**What the medicine looks like**

The gums are brown/green in slivers of 8 mg and supplied in packs of 8, 10, 20, 75, 150, 195 and 315 pieces. Not all pack sizes may be available.

**Who makes nicotine?**

Product Licence holder and Manufacturer:

Wyeth UK Ltd, Woolmer Green, Hampshire, GU56 7EB, UK.