Therapy (NRT) for.
The number of gums you should be using, when you should take them, and how often you can take it. Steadily reduce the number of gums you use per day.

What to use Nicorette Gum
The number of Nicorette Gums you use each day will depend on how many cigarettes you smoke and how strong they are. See the dosing table to find out the dose you should take.

The 2 mg gums should be used by people who smoke 20 or fewer cigarettes each day or by heavier smokers when they are cutting down the number and strength of the Nicorette gums they are using.

The 4 mg gums should be used by people who smoke more than 20 cigarettes per day.

Children under 18 years
Do not give this product to children under 18 years of age.

How to chew Nicorette Gum – The Nicorette Chewing Technique
The method of chewing Nicorette Gum is not the same as for ordinary chewing gum. Nicorette Gum is chewed to release nicotine then rested so that nicotine can be taken in through the lining of the mouth. If Nicorette Gum is chewed continuously, the nicotine is released too quickly and is swallowed. This may irritate your throat, upset your stomach or give you hiccups.

If you have false teeth you may have difficulty chewing the gum as Nicorette Gum can stick to them and on rare occasions, damage dentures. If you experience a problem, other types of nicotine replacement therapy such as a skin patch, inhaler or lozenge may be more suitable for you.

The Nicorette Chewing Technique
1. Chew slowly until taste becomes strong.
2. Rest between gum and cheek.
3. Chew again when the taste has faded.

► 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 carefully.

How to stop smoking: your choice
Because smoking is an addiction, you may find it difficult to give up. From time to time you may still have strong urges to smoke but if you follow these recommendations, you have a good chance of quitting. Some people may find it easier to set a quit date and stop smoking immediately. Others who are unable or not ready to stop smoking abruptly, may benefit from gradually reducing the number of cigarettes they smoke each day until they feel able to stop completely.

If you find it hard to stop smoking using Nicorette Gums, you are warned that you will start smoking again without them or you find it difficult to reduce the number of Nicorette Gums you are using, talk to your doctor, nurse or pharmacist. Remember, Nicorette Gums are not intended as a substitute for smoking, they are an aid to give up.

Use one of the three options which follows:

1. Stopping Immediately
The idea is to stop smoking immediately and use the gum to relieve the cravings to smoke. After achieving this you then stop using the gums.

2. Adults aged 18 years and over
See the following instruction which shows the basic step by step process. The times given below are the longest amount of time they should take, and you should try to achieve your move to the next step in the shortest time possible.

Make sure that you read the instructions for each step in the information which follows.

Step 1: Set a date to quit and stop smoking completely.
Step 2: Use the gum for up to 12 weeks (3 months) to relieve your cravings to smoke. See the dosing table in "When to use Nicorette Gum" to decide which strength of gum to use and how often you can take it. Steadily reduce the number of gums you use per day until you have given up Nicorette gum completely.

► For those using the 4 mg Nicorette Gum, the use of 2 mg Gums may be helpful when withdrawing from treatment.

► You might feel a sudden craving to smoke long after you have given up smoking and stopped using Nicorette Gum. Remember you can use nicotine replacement therapy again if this should happen.

1. Stopping Gradually
The idea is to stop by gradually replacing some of your cigarettes with the gum. After achieving this you then give up cigarettes completely while using the gum. Finally, you give up using the gum.

2. Adults aged 18 years and over
See the following instruction which shows the basic step by step process. The times given for steps 2 and 3 are the longest they should take, and you should try to achieve your move to the next step in the shortest time possible.

Make sure that you read the instructions for each step in the information which follows.

Step 1: Work out how many cigarettes you smoke per day. Set a date to start reducing the number of cigarettes you smoke.
Step 2: Start reducing. Over the next few months, reduce the number of cigarettes you smoke by using Nicorette Gum when you feel the urge to smoke, until you feel ready to stop completely. See the dosing table in "When to use Nicorette Gum" to decide which strength of gum to use and how often you can take it.

► For those using the 4 mg Nicorette Gum, the use of 2 mg Gums may be helpful when withdrawing from treatment.

► If after 6 weeks you have not reduced the number of cigarettes you smoke, ask your doctor, nurse or pharmacist for advice.

1. An attempt to stop smoking completely has not been made after 6 months, ask your doctor nurse or pharmacist for advice.
Step 3: Stop smoking. Cut out all cigarettes and continue using the gum for up to 3 months to relieve your cravings to smoke.

Step 4: Start reducing the use of the gum. You should try to use fewer pieces of gum each day. When you are using only one or two pieces per day, you should stop completely.

! During times you cannot smoke
If you are a smoker and are in a situation where you are prohibited from smoking or it is inconvenient to smoke (e.g. in a smoke-free area such as on a plane or at the cinema), you can use Nicorette Gum to relieve any cravings you may experience.

! Adults aged 18 years and over
If you smoke less than 20 cigarettes per day, you should use the 2mg gum; if you smoke 20 or more cigarettes you should use the 4mg gum. Chew the gum using the correct chewing technique described in Section 3. Do not use more than 15 pieces of gum per day.

! If you use more Nicorette Gum than you should
If you have used more than the recommended dosage you may experience nausea (feeling sick), salivation, pain in your abdomen, diarrhoea, sweating, headache, dizziness, hearing disturbance or weakness.

➤ If you do 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.

! If a child has used or swallowed the gums
➤ Contact a doctor or your nearest hospital Accident and Emergency department immediately. Nicotine ingestion by a child may result in severe poisoning.

4. Possible side-effects
Like all medicines, this medicine can cause side-effects, although not everyone gets them. 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, restlessness, poor
concentration, increased appetite or weight gain, urges to smoke (craving), night time
awakening or sleep disturbance and lowering of heart rate, dizziness, coughs and colds,
constipation, mouth ulcers or bleeding in the mouth.

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 and hiccupping
(due to excessive swallowing of nicotine).

Side-effects of Nicorette Gum
Nicorette Gum can sometimes cause a slight irritation of the mouth and throat at the start of the treatment. It may also cause increased salivation. The gum may occasionally stick to dentures and in rare cases damage them.

If you experience any of the following, stop using the gum and seek medical help immediately:
- Swelling of the face, lips, tongue, throat or other parts of the body, wheezing or difficulty breathing or swallowing
- Chest pain, palpitations, an abnormal or fast heart beat
- Pins and needles

Other side-effects include:
- Very common side-effects (may affect more than 1 in 10 people):
  - headache
  - feeling sick (nausea)
  - hiccups
  - cough and irritation of the throat
- Common side-effects (may affect up to 1 in 10 people):
  - allergic reaction
  - vomiting
  - diarrhoea
  - burning sensation in the mouth
  - taste disturbance or loss of taste
  - pins and needles
  - dry mouth
  - indigestion or excessive gas or wind
  - increased salivation
  - sore and inflamed mouth
  - tiredness (fatigue)
  - stomach pain

Uncommon side-effects (may affect up to 1 in 100 people):
- abnormal dreams
- redness or itching of the skin or skin rash
- chest palpitations or fast heart rate or beat
- sudden reddening of the face and/or neck
- high blood pressure
- sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath
- loss or damage to voice
- shortness of breath
- nasal congestion
- sneezing
- throat tightness
- burping (belching)
- swollen, red, sore tongue
- blisters in the mouth
- numbness or tingling of the mouth
- hives (urticaria)

- excessive sweating
- pain in jaw
- aching muscles, muscle tenderness or weakness not caused by exercise
- chest discomfort and pain
- general feeling of discomfort or being unwell or out of sorts (malaise)

Rare side-effects (may affect up to 1 in 1000 people):
- difficulty in swallowing
- decreased feeling or sensitivity, especially in the mouth
- feeling of wanting to be sick (retching)

Side-effects with unknown frequency
- allergic reactions (swelling of the mouth, lips, throat and tongue, itching of the skin, swelling of skin, ulceration and inflammation of the lining of the mouth).
- blurred vision, watery eyes
- stomach discomfort
- dry throat, lip pain
- redness of the skin
- muscle tightness

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nicorette Gum
- Keep Nicorette Gum out of the sight and reach of children and animals.
- Do not store Nicorette Gum above 25°C.
- Do not use this medicine after the expiry date which is stated on the carton and blister after “EXP”. The expiry date refers to the last day of that month.
- Dispose of Nicorette Gum sensibly.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Nicorette Gum contains
Nicorette 4mg meditated chewing gum contains 4 milligrams (mg) of nicotine (the active ingredient). Other ingredients are chewing gum base (contains butylhydroxytoluene (E321)), sorbitol (E420), sodium carbonate, quinoline yellow (E104), flavourings, polacrilin, glycercer and talc.
What Nicorette Gum looks like and contents of the pack
The gums are yellow and square, blister packed in sheets of 15. Nicorette Gum (classic) is supplied as 30 or 210 packs. Not all pack sizes may be marketed.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath
Manufacturer
The manufacturer is McNeil AB, Helsingborg, Sweden.
PPA465/1876
Nicorette is a registered trademark of McNeil AB.

For further information on smoking cessation please ring the national smokers quit line on 1800 201 203 or visit www.quit.ie

This leaflet was prepared by PCO Manufacturing in May 2018