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# Information for the user

# NicAssist Ice Mint Gum (Nicotine)

**Boots NicAssist Ice Mint 2 mg Gum**
**Boots NicAssist Ice Mint 4 mg Gum**

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription to help relieve and/or prevent unpleasant withdrawal symptoms and cravings for nicotine when you are trying to give up smoking tobacco or vaping or for when you can't or don't want to smoke/vape cigarettes/e-cigarettes. However, you need to use it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

## What this medicine is for

This medicine contains nicotine which belongs to a group of medicines called nicotine replacement therapy (NRT). It acts to substitute the nicotine that you normally get from cigarettes/e-cigarettes and can be used to relieve and/or prevent unpleasant withdrawal symptoms and cravings for nicotine when you are stopping smoking/vaping, cutting down or for when you can't or don't want to smoke cigarettes or vape e-cigarettes.

It can be used to relieve the symptoms of nicotine withdrawal and to relieve and/or prevent the cravings for nicotine that you get:

- When you stop smoking/vaping completely
- When you cut down on the number of cigarettes/e-cigarettes you smoke/vape while you try to give up
- If you feel unable to stop smoking/vaping but you don't want to smoke/vape cigarettes/e-cigarettes or you want to avoid smoking causing harm to others, such as when you are with friends or family, or
- If you feel unable to stop smoking/vaping completely but you can't smoke/vape cigarettes/e-cigarettes, such as when you are at a party, in the pub, at work, on a plane or train etc.

This medicine can also be used when you are pregnant or breastfeeding to help you stop smoking, as the risk to your baby when using this product is far less than if you continue to smoke. The gum can also be used to help quit vaping, although the risks of continued vaping are not established. For more information see "Other important information".

When you stop smoking/vaping, cut down, or you can't or don't want to smoke/vape, your body misses the nicotine that you have been getting from the smoking/vaping. You may experience unpleasant feelings and a strong desire to smoke/vape ("craving").

This shows that you are dependent on nicotine. When you use the gum, nicotine is released and passes into your body through the lining of your mouth. The nicotine is sufficient to relieve and/or prevent the unpleasant withdrawal symptoms. It will also help to relieve and/or prevent your craving to smoke/vape but will not give you the "buzz" you get from a cigarette/e-cigarette.

You should always aim to stop smoking/vaping completely whilst using the gum. To help you cut down or stop smoking/vaping completely you should also try to use a behavioural support programme to increase your chances of successfully stopping smoking/vaping.

### Benefits you can get from using NRT instead of smoking/vaping

For the best effect, ensure that you use Boots NicAssist Ice Mint Gum correctly – see "How to use the gum".

**The benefits of stopping smoking tobacco far outweigh any potential risk from using nicotine from NRT.** It is the toxins in cigarette smoke such as **tar, lead, cyanide and ammonia that cause smoking related disease and death, not the nicotine.**

- **You may think that** smoking tobacco/vaping helps relieve feelings of anxiety and stress, but it does not deal with the cause of the stress. In addition, the feeling of relaxation after smoking/vaping is temporary, with withdrawal symptoms and cravings soon returning

**NRT can help relieve nicotine withdrawal symptoms such as irritability, low mood, anxiety, restlessness and cravings** when used in place of cigarettes/e-cigarettes.

- **NRT may benefit** smokers/vapers who want to quit, by helping to **control weight gain** that may be experienced when trying to stop smoking/vaping

Use of NRT is safer than smoking tobacco but as soon as you are ready, you should aim to stop smoking/vaping completely. The effects of vaping on your body are not established.

## Before you use this medicine

This medicine can be used by adults and children of 12 years and over. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

### ✗ Do not use:

- **If you are allergic** to any of the ingredients in this medicine (see **"What is in this medicine"**)
- **If you are a child under 12 years of age**

### ! Talk to your pharmacist, nurse or doctor:

- If you are in hospital because of heart disease (e.g. heart attack, chest pain, problems with your heart rate or rhythm, stroke, angina or high blood pressure) – try to give up smoking first without using NRT. However, once you are out of hospital, if you still need help to stop smoking, you can use this medicine. For other heart conditions that do not require you to be in hospital, using NRT is better than continuing to smoke. The risks of continued vaping are not yet established.
- If you have diabetes – monitor your blood sugar levels more often when you start using this medicine. You may find that you need to adjust the amount of insulin that you use, or the amount of tablets that you take (ask your doctor or diabetes nurse about this)
- If you have an ulcer in your stomach or upper intestine or problems such as pain or swelling of the stomach or oesophagus (the passage between your mouth and stomach)
- If your liver or kidneys do not work properly
- If you have an overactive thyroid gland
- If you have high blood pressure due to a tumour near your kidney (your doctor may have told you that you have a condition called phaeochromocytoma)
- If you are taking other medicines regularly prescribed by your doctor (see **"If you take other medicines"**)
- If you have ever experienced seizures (fits)
- If you have quit smoking/vaping and want to stop using the gum but are finding this difficult.
- If you are pregnant or breastfeeding (see **"Other important information"**)

## Other important information

**If you are pregnant:** You should try to stop smoking/vaping without using NRT.

However, if you still need help to stop smoking, you can use this product as the risk to your baby is far less than if you continue to smoke. You should talk to your pharmacist, nurse or doctor for more advice. The effects of vaping on babies and children are not established.

NRT products that are used intermittently, such as this one, may be preferable to nicotine patches. However, if you feel sick or are sick (morning sickness) the patches may be better for you. If you do use nicotine patches they should be taken off before bedtime. The effects of vaping on your body during pregnancy are not established.

**If you are breastfeeding:** You should try to stop smoking/vaping without using NRT.

However, if you still need help to stop smoking/vaping, it is recommended that you use NRT products that are used intermittently, not patches. You should talk to your pharmacist, nurse or doctor for more advice.

Breastfeeding your baby just before you use the gum makes sure that your baby gets the smallest amount of nicotine possible.

The amount of nicotine that your baby may receive when you are using the gum or other NRT products is much smaller and less harmful than the second-hand smoke they would inhale if you smoked. The effects of vaping on your body during breastfeeding are not established. Tobacco smoke causes breathing and other health problems in babies and children. The effects of vaping on babies and children are not established. If your husband, partner or other family members smoke/vape too, try to get them to give up with you.

**Nicotine products and children:** Nicotine can be very dangerous to children. The amount of nicotine tolerated by adults and adolescents can make children very ill, and can sometimes be fatal. Do not leave your gum where children may get hold of it.

**Some of the ingredients can cause problems:**

- The chewing gum base contains butylated hydroxytoluene (E321), an anti-oxidant. May cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.
- The chewing gum contains polysorbate 80 which can cause allergic reactions.

**Information about some of the ingredients in this medicine:** This medicine contains less than 1 mmol sodium (23 mg) in each chewing gum, that is to say essentially 'sodium - free'.

## If you take other medicines

Before you use this medicine, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Theophylline, clozapine, ropinirole – your doctor may want to monitor the amount of medicine that you take

When you stop smoking or reduce the number of cigarettes you smoke, your metabolism slows down. This can mean that some medicines may stay in your body longer than usual.

If you take any medicine on a regular basis, tell your doctor that you intend to stop smoking or reduce the number of cigarettes you smoke and follow his or her advice about these other medicines.

## ✓ How and when to use this medicine

Check the foil is not broken before use. If it is, do not use that gum.

### When to use the gum

Read all of the following information carefully before using the gum:

- Follow the instructions in the table, which shows when you should use the gum and the maximum amount of gums you should be using each day.
- See the "How to use the gum" instructions to make sure that you chew the gum correctly to ensure that nicotine is released and passes into your body through the lining of your mouth.
- The strength and number of gums you use each day will depend on how many cigarettes/e-cigarettes you smoke/vape and how strong they are.
- The 2 mg gum should be used for those who smoke 20 cigarettes or fewer a day or by light to moderate vapers (e.g. vape infrequently or use low strength e-liquid). If the 2 mg gum does not relieve the urge to vape, 4 mg gum should be used.
- The 4 mg gum should be used for those who smoke more than 20 cigarettes a day or by heavy vapers (e.g. vape frequently or use high strength e-liquid).

However, the 2 mg gum will also be useful for heavier smokers/vapers once they have quit, as they gradually start to reduce the strength and

number of gums they use each day.
- Boots NicAssist Ice Mint Gum should be used **whenever** the urge to smoke/vape is felt or when you would **normally expect** to have cravings to smoke/vape
- It is recommended that to successfully reduce the amount of cigarettes/e-cigarettes you smoke/vape or stop smoking/vaping completely you should use the gums as often as possible and it is up to you how many gums you use (up to 15 a day) and for how long
- **If you are ready to stop smoking/vaping completely,** you should use the gums, when needed, to replace all of your cigarettes/e-cigarettes. As soon as you feel ready (this could be after a number of weeks or months) you should reduce the strength, if required, and number of gums used per day until you no longer need to use the gums
- **If you are not ready to stop smoking/vaping completely,** you should replace as many cigarettes/e-cigarettes as possible with the gums. Boots NicAssist Ice Mint Gum provides a safer alternative to smoking tobacco for you and those around you, as it is the toxins in cigarette smoke that cause harm, not the nicotine. The effects of vaping on your body are not established.
- Reducing the amount of cigarettes/e-cigarettes you smoke/vape may also help you to become more motivated to stop smoking/vaping. As soon as you feel ready, you should aim to stop smoking/vaping completely
- **You can also use the gums when you can't or don't want to smoke/vape,** such as social occasions e.g. at a party, in the pub, or for when you are at work, or on a plane or train etc.

When making an attempt to stop smoking/vaping completely behavioural therapy, advice and support will normally improve the success rate.

### Adults and children of 12 years and over

| Number of cigarettes/e-cigarettes you smoke/vape per day | How many gums and when to use |
|---|---|
| 20 cigarettes or fewer or light to moderate vapers | **One 2 mg gum** as required to relieve and/or prevent cravings |
| More than 20 cigarettes or heavy vapers | **One 4 mg gum** as required to relieve and/or prevent cravings |
| Use only one piece of gum at a time. **Don't use more than** 15 gums per day. | |

You should always aim to stop smoking/vaping completely whilst using the gums.

**If you are unable to reduce the strength or number** of gums you are using you should ask for help and advice from a pharmacist, nurse or doctor.

Do not give this medicine to children under 12 years of age.

## How to use the gum

The method of chewing Boots NicAssist Ice Mint Gum is not the same as for ordinary chewing gum. If the gum is chewed all the time (continuously), the nicotine is released too quickly and is swallowed. This may irritate your throat, upset your stomach or give you hiccups.

The gum should be chewed and then rested to release the nicotine, which is taken in through the lining of the mouth.

If you have false teeth you may have difficulty chewing the gum as it may stick to them, and on rare occasions, damage dentures. If you experience a problem, other types of nicotine replacement therapy such as skin patches, inhalator, lozenges or microtabs may be more suitable for you.

### Chewing technique

1 Chew slowly until taste becomes strong
2 Rest the gum between your gums and cheek
3 For about the next half an hour, when the taste fades, chew the gum again. After this time the gum will have lost its strength and you should dispose of it carefully

! **If you use too many gums:** You may get the following – nausea (feeling sick), vomiting, increased salivation, pain in your stomach, diarrhoea, sweating, headache, dizziness, hearing disturbance, weakness. **If this happens stop using the gums and do not smoke/vape. Contact a doctor or hospital casualty department straight away.** Take the medicine and this leaflet with you.

**If a child under 12 accidentally uses, swallows, sucks or chews** some of this medicine take them to casualty immediately. Take the medicine and this leaflet with you. Nicotine ingestion by a child may cause severe poisoning.

## Possible side effects

Most people can use this medicine without any problems but sometimes you may notice some side effects. Many of these effects are due to nicotine, they may also happen when you smoke/vape.

**If you notice any of the following serious side effects, stop using the medicine, do not smoke/vape and see your doctor as soon as possible:**
- You develop a fast, slow or irregular heart beat
- You have an allergic reaction to the gum such as rash, itching or swelling of the tongue, mouth or throat (go straight to casualty if severe)
- You experience seizures (fits)

**Effects related to stopping smoking/vaping** (nicotine withdrawal)
You may experience unwanted effects because by stopping smoking/vaping or using the gums when you are unable to smoke/vape you have reduced the amount of nicotine you are getting. You may also experience these effects if you use too few gums before you are ready to reduce your nicotine intake.
These effects include:
- Irritability or aggression, feeling low, anxiety, restlessness
- Poor concentration, urges to smoke (craving), night time awakening or sleep disturbance
- Increased appetite or weight gain
- Lowering of heart rate
- Dizziness, lightheadedness, blurry vision, nausea
- Cough
- Constipation
- Bleeding gums
- 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 or vaping. You may be able to relieve these effects by using the gums less often. These effects include:
- Feeling faint, feeling sick (nausea), headache
- Hiccupping (due to swallowing too much nicotine when you chew)

**Side effects of the gum**
Very common side effects:
(more than 1 in every 10 people are affected)
- Headache
- Sore mouth or throat, throat irritation
- Feeling sick, hiccups

Common side effects:
(less than 1 in every 10 people are affected)
- Allergic reactions
- Dizziness, taste changes, pins and needles
- Cough
- Stomach pain, heartburn, diarrhoea, wind
- Dry mouth, being sick, inflammation of the mouth, increase in saliva
- Burning sensation in the mouth, feeling tired

Uncommon side effects:
(less than 1 in every 100 people are affected)
- Abnormal dreams
- Changes in heart rhythm (you may notice a fast heart rate or beat)
- Flushing, high blood pressure
- Throat tightness, difficulty in breathing, shortness of breath, hoarseness of the voice
- Nasal congestion, sneezing
- Belching, inflammation of the tongue, mouth ulcers, tingling mouth
- Itching, skin rash, hives, excess sweating
- Jaw pain
- Generally feeling unwell or weak, chest pains

Rare side effects:
(less than 1 in every 1,000 people are affected)
- Swelling of the mouth, lips, throat and tongue, itching of the skin, swelling of the skin, ulceration and swelling of the lining of the mouth (allergic reactions)
- Difficulty swallowing, retching, mouth feeling numb

Very rare side effects:
(less than 1 in 10,000 people are affected)
- Abnormal beating of the heart

Side effects with an unknown frequency:
- Severe allergic reaction
- Blurred vision, watery eyes
- Dry throat, stomach discomfort, lip pain
- Tightness of the jaw
- Redness of the skin
- A fast and irregular heartbeat (atrial fibrillation)

! When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

### 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 on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## How to store and dispose of this medicine

Do not store above 25ºC.

**Keep this medicine in a safe place out of the sight and reach of children and animals,** preferably in a locked cupboard. Nicotine in high amounts can be very dangerous and sometimes fatal if used or swallowed by children.

Store the gum in the original pack.

Use by the date on the foil or the end flap of the carton. After this date return any unused product to your nearest pharmacy for safe disposal.

Dispose of any used gum sensibly and away from children and animals.

## What is in this medicine

This pack contains 105 pieces of medicated chewing gum in blister strips of 15's. Each gum contains nicotine 2 mg or nicotine 4 mg, which is the active ingredient.

As well as the active ingredient, the gum also contains chewing gum base (containing butylated hydroxytoluene E321), xylitol, peppermint oil, sodium carbonate, acesulfame potassium, levomenthol, magnesium oxide, talc, flavour (winterfresh), hypromellose, sucralose, polysorbate 80, purified water, starch, titanium dioxide (E171), carnauba wax.

The 2 mg gum also contains sodium bicarbonate. The 4 mg gum also contains quinoline yellow (E104).

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

## Who makes this medicine

This product is manufactured for The Boots Company PLC, Nottingham, NG2 3AA by McNeil AB, Helsingborg, Sweden.

The Marketing Authorisation holder is McNeil Products Ltd., 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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If you would like any further information about this product, please contact The Boots Company PLC, Nottingham, NG2 3AA.

### Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge:

**0800 198 5000** (UK only)

Please be ready to give the following information:

| Product name | Reference Number |
|---|---|
| Boots NicAssist Ice Mint 2 mg Gum | 15513/0152 |
| Boots NicAssist Ice Mint 4 mg Gum | 15513/0153 |

This is a service provided by the Royal National Institute of Blind People.

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