

# nicorette®

fruit  
2 mg and 4 mg Lozenge  
nicotine  
compressed lozenge

What you should know about  
nicorette® fruit lozenge

nicorette®  
fruit 2 mg Lozenge  
(2 mg nicotine compressed  
lozenge)

nicorette®  
fruit 4 mg Lozenge  
(4 mg nicotine compressed  
lozenge)

## nicorette®

PACKAGE LEAFLET:  
INFORMATION FOR THE USER

652594



Please read this leaflet carefully before you start using this medicine. It provides useful information on how to use it safely. Keep the leaflet, you might need it again.

If you think you are having side-effects, have any questions or are not sure about anything **please ask your doctor, pharmacist or nurse.**

### 1 What this medicine is for

**NICORETTE® fruit lozenge is a nicotine replacement therapy (NRT).**

It is used to relieve and /or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking tobacco or vaping or when cutting down the number of cigarettes/e-cigarettes you smoke/vape.

NICORETTE® fruit lozenge can also be used when you are pregnant or breastfeeding 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 breastfeeding*” section.

NICORETTE® fruit lozenge can also be used to help quit vaping, although the risks of continued vaping are not established.

Ideally you should always aim to stop smoking and vaping. You can use NICORETTE® fruit lozenge to achieve this by using it to completely replace all your cigarettes/e-cigarettes.

However NICORETTE® fruit lozenge can also be used in other ways,

- if you feel unable to stop smoking/vaping completely, or wish to replace certain cigarettes/e-cigarettes, it can help you to cut down the number



of cigarettes/e-cigarettes you smoke/vape,

- at those times when you can't or do not want to smoke/vape. For example,
  - Where you don't want to smoke/vape and want to avoid harm to others e.g. children or family.
  - Smoke/vape free areas e.g. pub, work, public transport e.g. 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.

### What does nicorette® fruit lozenge do?

When you stop smoking/vaping or cut down the number of cigarettes/e-cigarettes you smoke/vape, your body misses the nicotine that you have been absorbing. You may experience unpleasant feelings and a strong desire to smoke/vape (craving). This indicates that you were dependent on nicotine.

When you use NICORETTE® fruit lozenge, nicotine is released and passes into your body through the lining of your mouth. The nicotine released is sufficient to relieve the unpleasant nicotine withdrawal symptoms.

It will also help to stop your craving to smoke/vape but will not give you the “buzz” you get from smoking a cigarette or vaping an e-cigarette.

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

For the best effect, ensure that you use NICORETTE® fruit lozenge correctly – see “*How to Use NICORETTE® fruit lozenge*”.

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 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 and 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.

### 2 Before using this medicine

#### ❗ Do not use nicorette® fruit lozenge:

- if you have an allergy to nicotine or any of the other ingredients.
- if you are a child under 12 years of age.

#### ⚠ Talk to your doctor, pharmacist or nurse...

- if you are pregnant or breastfeeding – you may be able to use nicotine replacement therapy (NRT) to help you give up smoking/vaping but you should try to give up without it. See “*If you are pregnant or breastfeeding*” section.

- if you are in hospital because of heart disease (including heart attack, chest pain, 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. **The risks of continued vaping are not yet established.**

- 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 liver or kidney disease.
- if you have an overactive thyroid gland or have a phaeochromocytoma (a tumour of the adrenal gland that can affect blood pressure) – your doctor will have told you this.

- if you have diabetes – monitor your blood sugar levels more often when starting to use nicorette fruit lozenge as you may find your insulin or medication requirements alter.

- if you are taking any other medicines such as theophylline, clozapine or ropinirole. Stopping smoking or cutting down may require the dose of these medicines to be adjusted.

- if you have ever experienced seizures (fits)

- if you have quit smoking/vaping and want to stop using the lozenges but are finding this difficult.

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

#### ⚠ If you are pregnant or breastfeeding

If you are pregnant:

- 1) Firstly, you should try to give up smoking/vaping without NRT. **Stopping completely is by far the best option. The earlier and quicker you do this the better it is for you and your baby.**

- 2) Secondly, if you can't manage this, you can use NRT as a safer alternative to smoking as the risks to your baby are far less than smoking, however you should talk to your doctor, pharmacist or nurse for advice. The effects of vaping on babies and children are not established. Products that are used intermittently, including NICORETTE® fruit lozenge, may be preferable to nicotine patches. However, patches may be more suitable instead if you have nausea or sickness. If you do use patches take them off before going to bed at night.

#### If you are breastfeeding:

- 1) Firstly, you should try to give up smoking/vaping without NRT.
- 2) Secondly, if you can't manage this you are best to use NRT products that are used intermittently (not patches), however you should talk to your doctor, pharmacist or nurse for advice. Breastfeed just before you use NICORETTE® fruit lozenge to ensure

that the baby gets the smallest amount of nicotine possible.

If you do 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 inhale if you smoked. The effects of vaping on your body during pregnancy and breastfeeding are not established. Tobacco smoke produces breathing and other problems in babies and children. The effects of vaping on babies and children are not established.

#### 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 lozenges where children may get hold of them.

#### ⚠ Choking hazard

Keep out of the sight and reach of children and use with caution if you have problems with breathing or swallowing.

#### ⚠ Important information about some of the ingredients

This medicine contains less than 1 mmol sodium (23 mg) in each lozenge, that is to say essentially ‘sodium- free’.

NICORETTE® fruit lozenge contains polysorbate 80 which can cause allergic reactions.

This medicinal product also contains a small amount of sulphites, coming from the flavour, which may rarely cause severe hypersensitivity reactions and bronchospasm.

### 3 How and when to use this medicine



#### TO OPEN:

1. Gently press the tab on which it is written 'press here'
2. At the same time, pull the top of the box forcefully

#### TO CLOSE: Push in the top of the box

#### ❶ How to use nicorette® fruit lozenge

Place the lozenge in the mouth. Allow it to slowly dissolve. This will release nicotine, which you will absorb through the lining of your mouth. NICORETTE® fruit lozenge should NOT be chewed or swallowed.

#### ❶ When to use nicorette® fruit lozenge

- The number of lozenges you use each day will depend on how many cigarettes/e-cigarettes you smoked/vaped and how strong they were. See dosing information below to find out the dose you should use.

- The 2 mg lozenges should be used by people who smoke 20 or fewer cigarettes a day or are light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) or by heavier smokers/vapers when they are cutting down the number and strength of the NICORETTE® lozenges they are using.

If the 2 mg lozenge does not relieve the urge to vape, 4 mg lozenge should be used.

- The 4 mg lozenges should be used by people who smoke more than 20 cigarettes a day or are heavy vapers (e.g. vape frequently or use high strength e-liquid).

If you are able to stop smoking/vaping you should use the lozenges, when needed, in place of cigarettes/e-cigarettes. As soon as you can (this could be after a number of weeks or months) you should reduce the number of lozenges until you have stopped using them completely. If you are unable to stop smoking/vaping or do not feel ready to quit at this time, you should replace as many cigarettes/e-cigarettes as possible with the lozenges. There are toxins in cigarettes that can cause harm to your body. The effects of vaping on your body are not established. NICORETTE® fruit lozenge provides a safer alternative to smoking tobacco, for both you and those around you. Reducing the amount of cigarettes/e-cigarettes may also help you to become more motivated to stop smoking/vaping. As soon as you are ready you should aim to stop smoking/vaping completely.

You can also use the lozenges on those occasions when you can't or don't want to smoke/vape e.g. social situations such as a party, in the pub or when at work. When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. If you have quit smoking/vaping and want to stop using NICORETTE® fruit lozenge but are finding this difficult you should contact

your doctor, pharmacist or nurse for advice. Below is the dosage information for the NICORETTE® fruit lozenge. This shows the number of lozenges you should be using and when you should use them.

ⓘ Children under 12 years

Do not give this product to children under 12 years.

ⓘ Adults and children aged 12 years and over

Age	Dosage of lozenge
Adults and children aged 12 years and over	One lozenge to be used as required to relieve cravings.
■ Most people use between 8 to 12 lozenges per day. ■ Do not use more than 15 lozenges per day. ■ Do not exceed the stated dose.	

⚠ If you have used too much nicotine® fruit lozenge

If you have used more than the recommended amount of NICORETTE® fruit lozenge or have smoked/vaped whilst using NICORETTE® fruit lozenge, you may experience nausea (feeling sick), vomiting, increased 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. Do not smoke or vape. Take this leaflet and the pack with you.

⚠ If a child has sucked, chewed or swallowed a nicotine® fruit lozenge

- Contact a doctor or your nearest hospital Accident and Emergency department immediately if a child under 12 years sucks, chews or swallows this medicine. Take this leaflet and the pack with you.

Nicotine ingestion by a child may result in severe poisoning.

4 Possible side-effects

Like all medicines, NICORETTE® fruit lozenge can have side-effects. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking/vaping.

Effects related to stopping smoking/vaping (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking/vaping you have reduced the amount of nicotine you are taking. You may also experience these effects if you under use NICORETTE® fruit lozenge 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
- lowering of heart rate
- dizziness, light-headedness, 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 e-cigarettes.

⚠ These effects include:

- feeling faint
- feeling sick (nausea)
- headache

Side-effects for nicotine® fruit lozenge

If you notice any of the following: fast heart rate/beat, abnormal beating of the heart, chest palpitations, shortness of breath, seizures (fits), or allergic reactions (swelling of the face, mouth, lips, throat or tongue, itching of the skin, swelling of the skin, ulceration or inflammation of the lining of the mouth, difficulty breathing or dizziness) stop taking NICORETTE® fruit lozenge, do not smoke/vape and contact a doctor immediately.

Very common side-effects:

(may affect more than 1 in 10 people):

- headache
- feeling sick (nausea)
- throat irritation
- hiccups
- sore mouth or throat

Common side-effects:

(may affect up to 1 in 10 people):

- allergic reactions (hypersensitivity)
- burning sensation in the mouth

- dizziness
- cough
- taste disturbance or loss of taste
- tingling or numbness of the hands and feet
- stomach pain or discomfort
- diarrhoea
- dry mouth
- indigestion
- excessive gas or wind
- increased salivation
- sore and inflamed mouth
- tiredness (fatigue)
- sickness (vomiting)

Uncommon side-effects:

(may affect up to 1 in 100 people):

- abnormal dreams
- 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
- blocked nose, sneezing
- throat tightness
- burping (belching)
- swollen, red, sore tongue
- mouth ulcers or blisters
- numbness or tingling of the mouth
- excessive sweating
- itching
- rash
- hives (urticaria)
- unusual weakness
- chest discomfort and pain
- jaw-muscle ache
- general feeling of discomfort or being unwell or out of sorts (malaise)

Rare side-effects:

(may affect up to 1 in 1,000 people):

- difficulty in swallowing
- decreased feeling of sensitivity, especially in the mouth
- retching (trying to be sick but bringing nothing up)

Other side-effects can include:

- blurred vision, watery eyes
- dry throat, lip pain
- stomach discomfort
- redness of the skin
- muscle tightness

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

- 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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.

5 Storing and disposal

- Keep NICORETTE® fruit lozenge out of the sight and reach of children and animals. Nicotine in high doses can be very dangerous and sometimes fatal if taken by children.
- In cardboard box: Store in the original container in order to protect from

moisture. Use within 3 months after removing the overwrap.

- In plastic bottle: Store in the original container in order to protect from moisture.
- Do not use the product after the 'Use before' date on the bottle or carton.
- Dispose of lozenges sensibly and away from children and animals. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What's in this medicine?

The active ingredient is nicotine. Each lozenge contains 2 or 4 milligrams of nicotine (as nicotine resinat). Other ingredients are: mannitol (E421), xanthan gum (E415), tutti frutti flavour (flavour contains orange oil, orange oil terpenes, isoamyl butyrate, citral, gum acacia (E414) and traces of sulphites), sodium carbonate anhydrous (E500), sucralose (E955), acesulfame potassium (E950), magnesium stearate (E470b), hypromellose (E464), titanium dioxide (E171), polysorbate 80, sepifilm gloss (contains hypromellose (E464), microcrystalline cellulose (E460), and potassium aluminium silicate (E555)).

What the medicine looks like

NICORETTE® fruit 2 mg lozenge is an oval, white to off-white lozenge imprinted with a “n” on one side and “2” on the other side.

NICORETTE® fruit 4 mg lozenge is an oval, white to off-white lozenge imprinted with a “n” on one side and “4” on the other side.

Pack types and pack sizes:

**2 mg lozenges:** Loose-fill packed in a plastic bottle (“Flip pack”) containing 20 lozenges and supplied in packs of 20 (1x20), 80 (4x20) and 160 (8x20) lozenges.  
or  
Carton containing 40 lozenges, supplied in packs of 40 (1x40), 80 (2x40) or 160 (4x40) lozenges.

**4 mg lozenges:** Loose-fill packed in a plastic bottle (“Flip pack”) containing 20 lozenges and supplied in packs of 20 (1x20) or 80 (4x20) lozenges.  
or  
Carton containing 40 lozenges, supplied in packs of 40 (1x40), 80 (2x40) and 160 (4x40) lozenges.

Not all pack types and pack sizes may be marketed.

Who makes nicotine® fruit lozenge?

The Product Licence holder is McNeil Products Ltd., 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

The manufacturer is McNeil AB, Helsingborg, Sweden.

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