

nicorette®

cools
2 mg and 4 mg Lozenge
nicotine
compressed lozenge

What you should know about
nicorette® cools lozenge

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

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

nicorette®

PACKAGE LEAFLET:
INFORMATION FOR THE USER

651539



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, nurse or pharmacist.**

1 What this medicine is for

NICORETTE® cools 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 or when cutting down the number of cigarettes you smoke.

NICORETTE® cools lozenge 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® cools lozenge to achieve this by using it to completely replace all your cigarettes.

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

- if you feel unable to stop smoking completely, or wish to replace certain cigarettes and therefore it can help you to cut down the number of cigarettes you smoke,
- at those times when you can't or do not want to smoke. For example,

- Where you don't want to smoke and avoid harm to others e.g children or family.
- Smoke 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® cools lozenge do?

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

When you use NICORETTE® cools 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 but 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, ensure that you use nicorette cools lozenge correctly – see "How to Use Nicorette® cools lozenge".

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 ammonia that cause smoking related disease 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 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. 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 nicorette® cools 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, nurse or pharmacist...

- If you are pregnant or breast-feeding – you may be able to use nicotine replacement therapy (NRT) to help you give up 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 attack,

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 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 cools 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 may require the dose of these medicines to be adjusted.
- If any of these applies, talk to your doctor, nurse or pharmacist.

▲ If you are pregnant or breast-feeding

If you are pregnant:

- 1) **Firstly, you should try to give up smoking 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.**

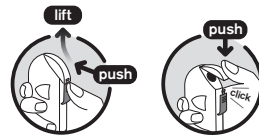
2) **Secondly, if you can't manage this, you can use NRT as a safer alternative to smoking** as the risks to your baby are far less than smoking, however you should talk to your doctor, nurse or pharmacist for advice.

Products that are used intermittently, including NICORETTE® cools lozenge, may be preferable to nicotine patches. However, patches may be more suitable if you have nausea or sickness. If you do use patches take them off before going to bed at night.

If you are breast-feeding:

- 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® cools 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. Tobacco smoke produces breathing and other problems in babies and children.



TO OPEN



TO CLOSE

3 How and when to use this medicine

① How to use nicorette® cools 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® cools lozenge should NOT be chewed or swallowed.

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

② When to use nicorette® cools lozenge

- If you smoke 20 or less cigarettes a day, the 2 mg nicotine lozenge will help relieve your cravings.
- The 4 mg lozenge should be used by people who smoke more than 20 cigarettes a day.

If you are able to stop smoking you should use the lozenge, when needed, in place of 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 or do not feel ready to quit at this time, you should replace as many cigarettes as possible with the lozenge. There are toxins in cigarettes that can cause harm to your body. NICORETTE® cools lozenge provides a safer alternative to smoking, for both you and those around you. Reducing the amount of cigarettes may also help you to become more motivated to stop smoking. As soon as you are ready you should aim to stop smoking completely.

You can also use the lozenge on those occasions when you can't or don't want to smoke 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 and want to stop using NICORETTE® cools lozenge but are finding this difficult you should contact your doctor, nurse or pharmacist for advice.

Below is the dosage information for the NICORETTE® cools lozenge. This shows the number of lozenges you should be using, when you should take them, how you should take them and the maximum amount of time you should be using Nicotine Replacement Therapy (NRT) for.

③ 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 taken as required to relieve cravings.

- Most people take between 8 to 12 lozenges per day.
- Do not take more than 15 lozenges per day.
- Do not exceed the stated dose.

If you have used too much nicorette® cools lozenge

If you have used more than the recommended amount of NICORETTE® cools lozenge 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 a nicorette® cools lozenge

➤ **Contact a doctor or your nearest hospital Accident and Emergency department immediately** if a child under 12 years uses, 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® cools lozenge can have side-effects. 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® cools 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

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

Side-effects for nicorette® cools lozenge

If you notice any of the following; fast heart rate/beat, abnormal beating of the heart, chest palpitations, shortness of

breath or allergic reactions (swelling of the face, mouth, lips, throat and tongue, itching of the skin, swelling of the skin, ulceration and inflammation of the lining of the mouth, difficulty in breathing and dizziness) stop taking NICORETTE® cools lozenge and contact a doctor immediately.

Very common side-effects:

(*may affect more than 1 in 10 people*):

- headache
- cough
- 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
- 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 dream
- 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
- feeling of wanting to be sick (vomit)

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

By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing and disposal

■ **Keep NICORETTE® cools 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 small children.

■ NICORETTE® cools lozenge does not require any special storage conditions.

■ Do not use the product after the 'Use before' date on the bottle, box or blister strip.

■ Dispose of lozenges sensibly 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 resinate).

Other ingredients are: Mannitol (E421), Xanthan gum (E415), Winterfresh Flavour, Sodium carbonate anhydrous, Sucralose (E955), Acesulfame potassium (E950), Magnesium stearate (E470b), Hypromellose (Methocel E3), Titanium

dioxide (E171), Sepifilm gloss, Polysorbate 80.

What the medicine looks like

NICORETTE® cools 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® cools 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:

Loose-fill packed in a plastic bottle ("Flip pack") containing 20 lozenges and supplied in packs of 20 (1x20) or 80 (4x20) lozenges.

Blister packed in sheets of 12 and contained in a cardboard box supplied in packs of 24 (2x12) lozenges. Not all pack types and pack sizes may be marketed.

Who makes nicorette® cools lozenge?

The Product Licence holder is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

The manufacturer is McNeil AB, Helsingborg, Sweden.

This leaflet was prepared in June 2017. ©