

Package leaflet:  
information for the user

## Nicorette Cools 2 mg Lozenge Nicorette Cools 4 mg Lozenge

nicotine  
**Read all of this leaflet carefully  
before you start taking this medicine  
because it contains important  
information for you.**

Always take this medicine exactly as  
described in this leaflet or as your doctor  
or pharmacist has told you.

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

- If you get any side effects, talk to your  
doctor or pharmacist. This includes  
any possible side effects not listed in  
this leaflet. See section 4.

- You must talk to a doctor if after  
9 months you still have difficulties  
refraining from smoking, without the  
help of Nicorette Cools.

### What is in this leaflet:

1. What Nicorette Cools are and what  
they are used for
2. What you need to know before you  
take Nicorette Cools
3. How to use Nicorette Cools
4. Possible side effects
5. How to store Nicorette Cools
6. Contents of the pack and other  
information

## 1 What Nicorette Cools Are And What They Are Used For

This medicine is used to relieve  
withdrawal symptoms and reduce the  
cravings for nicotine that you get when  
you try to stop smoking or when you are  
cutting down the number of cigarettes  
you smoke while trying to stop smoking.  
The treatment is for adult smokers 18  
years and above.

Nicorette Cools 2 mg Lozenges are  
suitable for smokers who have a low  
nicotine dependency e.g., who either  
have their first cigarette of the day more  
than 30 minutes after waking up or who  
smoke 20 cigarettes or less per day.

Nicorette Cools 4 mg Lozenges are  
suitable for smokers with high nicotine  
dependency e.g., those smoking their  
first cigarette of the day within 30  
minutes after waking up or those who  
smoke more than 20 cigarettes per day.

This medicine can help you give up  
smoking straightaway or to cut down  
smoking before stopping completely. If  
you think you can stop smoking straight-  
away, then you should. However, if you  
feel this is a too big step, then you may  
wish to try cutting down the amount of  
cigarettes you smoke as a first step  
before stopping completely.  
See Section 3 "How to use Nicorette  
Cools" for further details.

Nicorette Cools relieves the nicotine  
withdrawal symptoms, including  
cravings, you get when you stop  
smoking. When your body suddenly  
stops getting nicotine from tobacco, you  
get hit by different kinds of unpleasant  
feelings called withdrawal symptoms,  
such as irritability, feeling angry or low,  
anxiety, restlessness, poor concentration,  
increased appetite or weight gain, urges  
to smoke (craving), night time awakening  
or sleep disturbance. The nicotine in  
Nicorette Cools can help prevent or  
reduce these unpleasant feelings and  
cravings for smoking.

To improve the chances of helping you  
to stop smoking, also seek counseling  
advice and support.

## 2 What you need to know before you take Nicorette Cools

### Do not use Nicorette Cools:

- if you are **allergic** to nicotine or any of  
the other ingredients of this medicine  
(listed in section 6).
- if you are under 12 years of age.
- if you have never smoked.

### Warnings and precautions

Talk to your doctor if you suffer from the  
following. You may still be able to use  
Nicorette Cools Lozenges, but need to  
discuss with your doctor first if you have:

- Recently had a **heart attack or stroke**
- **Chest pain** (unstable angina) or  
resting angina
- A **heart condition** that affects your  
heart rate or rhythm (arrhythmia)
- **High blood pressure** which is not  
being controlled by medicines
- Ever had **allergic reactions** that  
involve swelling of the lips, face and  
throat (angioedema) or itchy skin rash  
(urticaria). Using NRT can sometimes  
trigger this type of reaction
- Severe or moderate **liver disease**
- Severe **kidney disease**
- **Diabetes**
- An overactive **thyroid gland**
- A tumour of the **adrenal gland**  
(phaeochromocytoma)
- **Stomach or duodenal ulcer**
- **Oesophagitis**

This medicine should not be used by  
non-smokers.

### Children

The correct dose for adults could  
seriously poison, or even be fatal, for  
children. It is therefore essential to keep  
Nicorette Cools Lozenges out of sight  
and reach of children at all times.

### Other medicines and Nicorette Cools

Tell your doctor or pharmacist if you are  
taking, have recently taken any or might  
take any other medicines. This is  
especially important if you take  
medicines containing:

**theophylline** to treat asthma  
**tacrine** for Alzheimer's disease  
**clozapine** for schizophrenia  
**ropinirole** to treat Parkinson's disease.

### Taking Nicorette Cools with food and drink

Do not eat or drink when administering  
the lozenges.

### Pregnancy and breast-feeding

It is very important to stop smoking  
during **pregnancy** because it can result  
in poor growth of your baby. It can also  
lead to premature births or stillbirths. It is  
best if you can give up smoking without  
the use of medicines containing nicotine.  
If you cannot manage this, Nicorette  
Cools should only be used after  
consulting the healthcare professional  
who is managing your pregnancy, your  
family doctor or a doctor in a centre that  
is specialised in helping people quit  
smoking.

Nicorette Cools should be avoided  
during breast-feeding as nicotine is

found in breast milk and may affect your  
child. If your doctor has recommended  
you to use Nicorette Cools, the lozenge  
should be taken just after breast-feeding  
and not during the 2 hours before  
breast-feeding.

Smoking increases the risk of infertility in  
women and men. The effects of nicotine  
on fertility are unknown.

### Driving and using machines

No effects on the ability to drive cars or  
use machines have been observed.

Nicorette Cools contains less than  
1 mmol sodium (23 mg) per lozenge, i.e.  
is essentially 'sodium-free'.

## 3 How to use Nicorette Cools

Always use this medicine exactly as  
described in this leaflet or as your doctor  
or pharmacist has told you. Check with  
your doctor or pharmacist if you are not  
sure.

The instructions about how to use  
Nicorette Cools depend on whether you  
are:

- (a) stopping smoking immediately
- (b) stopping smoking gradually

### Adults (18 years and over)

#### (a) Stopping smoking immediately

The idea is to stop smoking  
immediately and use the lozenge, to  
relieve the cravings to smoke.

- Start by using 8 to 12 lozenges a  
day. Whenever you have an urge to  
smoke, one lozenge should be

placed in the mouth and allowed to  
dissolve.

- Use the lozenges like this for up to  
6 weeks, then gradually cut down  
the number of lozenges you use a  
day.
- Once you are using only 1 or 2  
lozenges a day, stop using them  
altogether. After you have given up  
you may sometimes feel a sudden  
craving for a cigarette. You can use  
a lozenge again if this happens.

#### (b) Stopping smoking gradually

The idea is to start by gradually  
replacing some of your cigarettes with  
the lozenge. After achieving this you  
then give up cigarettes completely  
while using the lozenge. Finally, you  
give up using the lozenge.

When you feel a strong urge to  
smoke, use a Nicorette Cools  
Lozenge instead of a cigarette to help  
you manage your cravings. Cut down  
the number of cigarettes you smoke  
per day as many as possible. If you  
have not been able to cut down the  
number of cigarettes you smoke each  
day after 6 weeks, talk to your  
healthcare professional.

As soon as you feel able, you should  
give up cigarettes completely. Follow  
the instructions for stopping smoking  
straightaway given above. Do this as  
soon as possible. If your attempt to  
stop smoking completely has not  
been successful within 6 months of  
starting the use of this medicine,  
speak to a healthcare professional.

Do not exceed the stated dose.  
Follow the instructions carefully and  
do not use more than 15 lozenges in  
one day (24 hours).

If you feel the need to use this  
medicine for longer than 9 months in  
total, you should ask a doctor for  
advice.

#### Children and adolescents

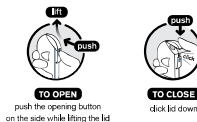
##### Adolescents 12-17 years

Nicorette Cools should only be used  
following advice from a healthcare  
professional.

##### Children under 12 years of age

This medicine must not be used by  
children under 12 years.

#### Instruction for use



This medicine is for oromucosal use. It is  
to be placed in the mouth where it is  
allowed to dissolve and release nicotine  
for absorption through the lining of the  
mouth into the body.

Put one lozenge in your mouth and from  
time to time move it from one side of  
your mouth to the other, until it is  
completely dissolved. This should usually

take less than 20 minutes. Do not chew the lozenge or swallow it whole. You should not eat or drink while a lozenge is in the mouth.

**If you are tempted to start smoking again**

If you are:

- worried that you may start smoking again
- finding it difficult to stop using the lozenges **completely talk to a health-care professional.**

If you do start to smoke again, they can advise you on how to get the best results from further courses of Nicotine Replacement Therapy (NRT).

**If you take more Nicorette Cools than you should**

Overdosing of nicotine may occur if you smoke at the same time as you take Nicorette Cools.

If a child takes this medicine, or if you have used more this medicine than you should, contact your doctor or go to the nearest hospital **immediately**. Doses of nicotine that are tolerated by adult smokers during treatment may produce severe symptoms of poisoning in **children** and may prove **fatal**.

The symptoms of overdose are feeling sick (nausea), vomiting, too much saliva, stomach pain, diarrhoea, sweating, headache, dizziness, changed hearing, and feeling very weak. At high doses, these symptoms may be followed by low blood pressure, weak and irregular

pulse, difficulty breathing, extreme tiredness, circulatory collapse and general convulsions.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Effects related to stopping smoking (nicotine withdrawal)

Some of the unwanted effects that you experience when stopping smoking can be withdrawal symptoms due to decreases in nicotine intake.

**These effects include:**

- Irritability, aggression, impatience or frustration
- Feeling anxious, restless or having difficulty concentrating
- Night time awakening or sleep disturbance
- Increased appetite or weight gain
- Feeling low
- Urges to smoke (craving)
- Lowering of heart rate
- Bleeding gums or mouth ulcers
- Dizziness or light-headedness
- Cough, sore throat, stuffy or runny nose
- Constipation

If you notice any of the following serious side effects stop taking Nicorette Cools

and contact a doctor immediately, as they may be a sign of severe allergy (*the frequency is not known: frequency cannot be estimated from the available data*):

- hives (a skin condition characterised by itching raised or red spots)
- swollen face, tongue or throat
- difficulty in breathing
- difficulty in swallowing

Most of the side effects occur during the early phase of use. During the first few days of treatment irritation in the mouth and throat may be experienced, however most users adapt to this with continued use.

**Other side effects that may occur:**

**Very common:** may affect more than 1 in 10 people:

- Cough
- Headache
- Hiccups
- Nausea (feeling sick)
- Throat, mouth or tongue irritation

**Common:** may affect up to 1 in 10 people:

- Local effects such as burning sensation, inflammation in the mouth, changes in taste perception
- Cold, warmth, tingling feeling in the skin
- Dry mouth or increased amounts of saliva
- Feelings of dyspepsia (indigestion)
- Pain or discomfort in tummy

(abdomen)

- Vomiting, flatulence or diarrhoea
- Heartburn
- Feeling tired (fatigue)
- Hypersensitivity (allergy)

**Uncommon:** may affect up to 1 in 100 people:

- Effects on the nose such as stuffiness, sneezing
- Wheezing (bronchospasm), or feeling like breathing requires more effort than usual (dyspnoea), throat tightness
- Skin flushing (blushing) or increased sweating
- Oral effects such as mouth tingling, inflammation of the tongue, mouth ulcers, damage to the lining of the mouth, or changes in the sound of your voice, pain in the mouth and throat, belching

- Feeling your heartbeats (palpitations), increase of heart rate, hypertension
- A fast and erratic heartbeat, which can be treated with appropriate medication

- Rash and/or itching
- Abnormal dreams
- Chest discomfort and pain
- Weakness, feeling unwell

**Rare:** may affect up to 1 in 1,000 people

- Difficulty swallowing, reduced sensations in the mouth
- Retching

**Not known:** frequency cannot be estimated from the available data:

- Blurred vision, increased tear production
- Dry throat, stomach discomfort, pain in the lips
- Redness of the skin

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

## 5 How to store Nicorette Cools

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the container and outer packaging after "Exp". The expiry date refers to the last day of the month.
- In polypropylene container: Store in the original polypropylene container in order to protect from moisture
- In blister: This medicinal product does not require any special storage conditions.

- Do not re-use the container for anything else as there may be Lozenge dust in the container which may deposit a fine coating on items within.
- 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 to protect the environment.

## 6 Contents of the pack and other information

**What Nicorette Cools contains**

**The active substance** is nicotine. Each lozenge contains 2 mg or 4 mg nicotine (as nicotine resinate).

**The other ingredients are lozenge core:** mannitol (E421), xanthan gum, Winterfresh RDE4-149 Spray dried (gum arabic (E414), peppermint, menthol and eucalyptol flavourings), sodium carbonate, anhydrous (E500)(i), sucralose (E955), acesulfame potassium (E950), magnesium stearate (E470b).

**Coating:** hypromellose (E464), Winterfresh RDE4-149 (peppermint, menthol and eucalyptol flavourings), titanium dioxide (E171), sucralose (E955), microcrystalline cellulose (E460), potassium aluminium silicate (E555), acesulfame potassium (E950), polysorbate 80 (E433),

**What Nicorette Cools looks like and contents of the pack**

An oval, white to off-white lozenge imprinted with an "n" on one side and "2" or "4" on the other side.

Pack sizes:  
Each plastic bottle contains 20 lozenges. Packs may contain 1, 4 or 8 bottles. Each cardboard box contains 2 blister charts of 12 lozenges. With and without a carrying case.

**Not all pack sizes may be marketed.**

**Marketing Authorisation Holder and Manufacturer**

MA Holder:

Johnson & Johnson (Ireland) Limited, Airton road, Tallaght, Dublin 24, Ireland.

Manufacturer:

McNeil AB, PO Box 491, Norrbroplatsen 2, SE-251 09 Helsingborg, Sweden.

**This medicinal product is authorised under the following names:**

**Austria, Finland:** Nicorette Ice mint

**Belgium, Germany, Luxembourg:**

Nicorette Freshmint

**Denmark, Iceland:** Nicorette Cooldrops

**Czech Republic:** Nicorette Mint

**Ireland:** Nicorette Cools

**Norway:** Nicorette

**Poland:** Nicorette Coolmint

**Sweden:** Nicorette Pepparmint

**For further information on smoking cessation please ring the national smokers quit line on 1800 201 203 or visit [www.quit.ie](http://www.quit.ie).**

This leaflet was last approved in July 2019