

Package leaflet:
information for the user
Nicorette Cools 2 mg lozenges
Nicorette Cools 4 mg lozenges
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 straightaway, 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**
- History of **epilepsy** or **seizure**

This medicine should not be used by non-smokers.

Lozenges can represent a choking hazard. Use with caution if you have trouble swallowing solids or liquids or if you frequently cough during or after swallowing.

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

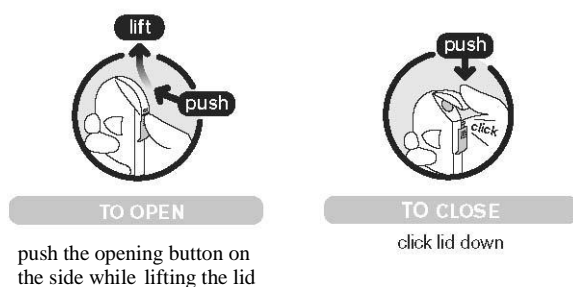
Adolescents 12 -17 years

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 healthcare 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 Nicorette Cools or if you have used more Nicorette Cools 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
- Seizure

Reporting of side effects

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, website: www.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 container in order to protect from moisture.
- 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)

Nicorette Cools Lozenges are sugar free.

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.

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 in the Member State of the EEA under the following name:

Finland	Nicorette Icemint
Austria, Belgium, Germany, Luxembourg	Nicorete Freshmint
Czech Republic	Nicorette Mint
Hungary, Slovakia	Nicorette Mint (4mg only)
Denmark, Iceland	Nicorette Cooldrops
Ireland	Nicorette Cools
Norway	Nicorette
Poland	Nicorette Coolmint
The Netherland	Nicorette Freshmint (4mg only)
Sweden	Nicorette Mint

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