

Package leaflet: Information for the user

Nicorette Novum 10 mg/16 hour transdermal patch
Nicorette Novum 15 mg/16 hour transdermal patch
Nicorette Novum 25 mg/16 hour transdermal patch

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, pharmacist or nurse have 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to healthcare personnel if you cannot taper off or quit smoking, or if you cannot stop using Nicorette. See section 3.

What is in this leaflet

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

1. What Nicorette Novum is and what it is used for

Nicorette belongs to a group of Medicinal products that are used to help you quit smoking.

The nicotine in Nicorette Novum relieves nicotine cravings and withdrawal symptoms when you quit smoking, thereby preventing relapse in smokers who are motivated to quit, or to facilitate smoking reduction (tapering before quitting) in smokers who are unable or unwilling to quit. The treatment is intended for smokers over the age of 18.

When the body suddenly no longer receives nicotine from tobacco, various discomforts known as withdrawal symptoms occur. Using Nicorette Novum transdermal patch can prevent or relieve such discomfort and cravings to smoke by continuing to supply your body with a small amount of nicotine for a transitional period. When you use Nicorette Novum transdermal patches, nicotine is slowly released and absorbed through the skin and transported through the body's bloodstream. Unlike cigarettes, Nicorette Novum does not contain harmful tar and carbon monoxide.

Nicorette transdermal patch should ideally be used in conjunction with a smoking cessation program. Advice and support normally increase the chance of success with your smoking cessation.

2. What you need to know before you use Nicorette Novum

Do not use Nicorette Novum

- 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, pharmacist, or nurse before using this medicine if you have any of the following conditions:

- have recently (within 3 months) had a **myocardial infarction** or **stroke**
- **chest pain** (unstable angina) or angina at rest
- **heart disease** that affects the heart rate or heart rhythm
- **hypertension** which is not being treated with medication
- severe or moderate **liver disease**
- severe **kidney disease**
- **diabetes**
- overactive **thyroid**
- tumor in **the adrenal medulla** (pheochromocytoma)
- **gastric ulcers** or **duodenal ulcers**
- **inflammation of the esophagus**
- history of **epilepsy** or **seizures**

However, the risk of continuing to smoke is always a greater danger than the use of Nicorette Novum transdermal patches.

If you have **skin problems** before you start using Nicorette Novum transdermal patches, or experience any symptoms during treatment, you should consult your doctor.

If you are going to have an MRI scan, the patch must be removed before the examination.

Children and adolescents

Adolescents aged 12 to 17 years should only use Nicorette Novum if they have received it by prescription from healthcare personnel. Nicorette Novum transdermal patch must not be used by children under 12 years.

Nicotine doses that are tolerated by adult smokers undergoing treatment can cause severe symptoms of intoxication and potentially fatal outcome in children. It is therefore important that Nicorette be kept out of the sight and reach of children at all times.

Other medicines and Nicorette

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

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

Pregnancy, breast-feeding and fertility

It is very important to quit smoking during pregnancy because smoking can impair the growth of the fetus. Smoking can also cause the baby to be born prematurely or lead to miscarriage. Ideally, you should be able to quit smoking without using nicotine-containing medicines. If you are unable to do this, Nicorette Novum should only be used after consulting the healthcare professional who is looking after your pregnancy, your doctor, or a healthcare professional who specializes in smoking cessation.

Nicorette Novum patches should be avoided during breast-feeding, as nicotine passes into breast milk and can affect your baby. Consult a healthcare professional before using Nicorette patches while breastfeeding

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 or operate machinery have been observed.

3. How to use Nicorette Novum

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

Nicorette Novum transdermal patch can be used alone or in combination with either Nicorette 2 mg chewing gum/lozenge/tablet or Nicorette Inhaler 10 mg or Nicorette oromucosal spray 1 mg/spray.

To minimize the risk of local irritation, the placement of the patch should be alternated between different application sites.

Advice and support can improve your chances of success.

Treatment with patches alone in high nicotine dependence (if you smoke more than 20 cigarettes/day)

1. A 25 mg/16 hour transdermal patch is applied in the morning and taken off at bedtime.
2. The duration of treatment is individual. After about 2 months, you should start to get rid of the nicotine addiction. This is done by gradually reducing the nicotine dose by using 15 mg/16 hours transdermal patch for 2 weeks and then 10 mg/16 hour transdermal patch for another 2 weeks.

Treatment with patches alone in low nicotine dependence (if you smoke no more than 20 cigarettes/day)

1. A 15 mg/16 hour transdermal patch is applied in the morning and taken off at bedtime.
2. The duration of treatment is individual. After about 2 months, you should start to get rid of the nicotine addiction. This is done by reducing the nicotine dose by using 10 mg/16 hours transdermal patch for 4 weeks.

Tabulated dosage instructions:

If you smoke more than 20 cigarettes/day			If you smoke no more than 20 cigarettes/day		
<i>Patch</i>		<i>Period</i>	<i>Patch</i>		<i>Period</i>
Step 1	25 mg/16 hours	Weeks 1-8			
Step 2	15 mg/16 hours	Weeks 9-10	Step 2	15 mg/16 hours	Weeks 1-8
Step 3	10 mg/16 hours	Weeks 11-12	Step 3	10 mg/16 hours	Weeks 9-12

Treatment longer than 6 months is not recommended. In some cases, a longer treatment period may be necessary to avoid relapse to smoking.

Treatment with transdermal patches in combination with Nicorette 2 mg chewing gum/lozenge/tablet (Microtab) or Nicorette Inhaler 10 mg or Nicorette oromucosal spray 1 mg/spray If you have a high nicotine dependence, experience nicotine cravings despite the use of nicotine replacement therapy or if you have been unsuccessful with a nicotine replacement therapy alone, you can use Nicorette Novum patches together with Nicorette 2 mg chewing gum/lozenge/tablet or Nicorette Inhaler 10 mg or Nicorette oromucosal spray 1 mg/spray for quick relief of nicotine cravings.

IMPORTANT Read the package leaflet of the Nicorette product you are using with the patch before use (enclosed in the respective package).

Initial combination therapy

You should quit smoking completely during the combination treatment.

A 25 mg/16 hour transdermal patch is applied in the morning and taken off at bedtime for 8 weeks.

Used either Nicorette gum 2 mg, Nicorette lozenge 2 mg, Nicorette tablet 2 mg, Nicorette inhaler 10 mg, or Nicorette oromucosal spray 1 mg/spray with the patch as follows:

Chewing gum, lozenge, tablet: Take a chewing gum or tablet when you feel the urge to smoke even though you are using Nicorette Novum patches. The usual dose is 5-6 chewing gums daily. Use no more than 24 chewing gums, 15 lozenges or 24 tablets daily.

Inhaler: Use your inhaler when you feel the urge to smoke even though you are using Nicorette Novum patches. The usual dose is 4-5 nicotine plugs daily, but no more than 12 nicotine plugs daily.

Oromucosal spray: Use the oromucosal spray when you feel the urge to smoke even though you are using Nicorette Novum patches. The usual dose is 13 sprays daily, but no more than 32 sprays daily.

After 8 weeks, gradually reduce the nicotine dose according to one of the following two options:

Weaning from nicotine medication – option 1

After the first 8 weeks, use patches with a lower strength:

1 patch 15 mg/16 hours daily for 2 weeks followed by 1 patch 10 mg/16 hours daily for another 2 weeks.

Use the same number of chewing gums/lozenges/tablets (2 mg) at the same time or Nicotine Plugs (10 mg) or sprays (1 mg/spray) as during the initial treatment.

After that, gradually reduce the number of chewing gums/lozenges/tablets/nicotine plugs or sprays. Do not use chewing gum/lozenges/tablets/the inhaler or the oromucosal spray for longer than 12 months from the start of treatment.

Weaning from nicotine medication – option 2

Discontinue the use of patches after the first 8 weeks. After that, gradually reduce the number of chewing gums/lozenges/tablets/nicotine plugs or sprays. Do not use chewing gum/lozenges/tablets/the inhaler or the oromucosal spray for longer than 12 months from the start of treatment.

Course of combination therapy in table form

Combining patches with just one of the options Nicorette chewing gum 2 mg/ Nicorette lozenge 2 mg/ Nicorette tablet 2 mg/Nicorette Inhaler 10 mg or Nicorette oromucosal spray 1 mg/spray.

Initial treatment			
Period	Patch	Flexible formulation (one of the following products can be used)	Dosage daily in combination with the patch
Weeks 1-8	1 patch 25 mg/16 hours daily	2 mg chewing gum	As needed. The usual dose is 5-6 chewing gums (max 24)
		2 mg lozenge	As needed. The usual dose is 5-6 lozenges (max 15)
		2 mg tablet (Microtab)	As needed. The usual dose is 5-6 tablets (max 24)
		inhaler	As needed. Regular dose 4-5 nicotine plugs (max 12)
		Oral spray	As needed. The usual dose is 13 sprays daily (but no more than 32 sprays/day)

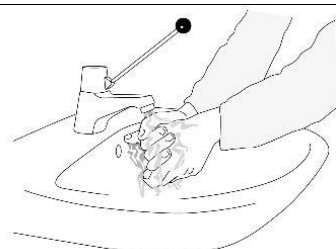
Weaning from nicotine medication – option 1		
Week 9-10	1 patch 15 mg/16 hours daily	Continue to use chewing gum/lozenges/tablets/inhaler/oral spray as needed
Weeks 11-12	1 patch 10 mg/16 hours daily	Continue to use chewing gum/lozenges/tablets/inhaler/oral spray as needed
Up to 12 months	---	Reduce the number of chewing gums/lozenges/tablets/nicotine plugs/sprays gradually
Weaning from nicotine medication – option 2		
Up to 12 months	---	Continue to reduce the number of chewing gums/lozenges/tablets/nicotine plugs/sprays gradually

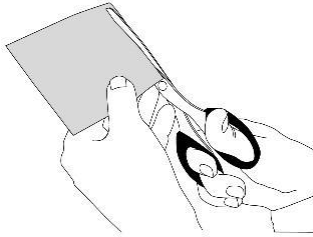
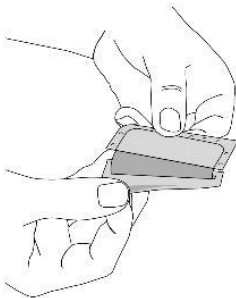
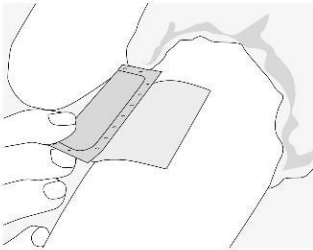
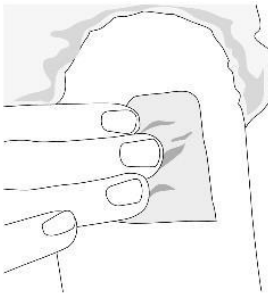
Instructions for use

Put the patch on when you wake up in the morning and take it off after about 16 hours before going to bed you in the evening.

You can bathe and shower as usual.

Here's how:

1. Wash your hands.	
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2. Cut the bag open along one side. Choose a place on the body with undamaged, clean and dry skin, preferably without hair, such as on the upper body, hip or upper arm. Do not put the patch in the same place every day, but alternate between the right and left upper arm, for example.	
3. Remove the patch from its sachet and then peel one part of the silvery aluminium backing away. Do not touch the sticky surface of the patch with your fingers.	
4. Place the sticky surface against the skin and peel off the remaining half of the silvery aluminium backing foil.	
5. Press the patch against the skin with the palm of your hand or fingers so that it adheres properly. Rub your fingers around the edge of the patch so that the patch is firmly attached.	
6. Wash your hands so that you do not pass the nicotine on, for example to your eyes.	

Fold the used patch with it *sticky side inward* and throw it in a place where children can't reach it. Take a new patch the next day and repeat steps 1-6.

If Nicorette Novum transdermal patch comes off and falls off, apply a new patch immediately to a different place and keep it on until you go to bed at night.

If you use more Nicorette Novum than you should

Nicotine overdose can occur if you smoke while using Nicorette Novum transdermal patches. If you have ingested too much medicine or if, for example if a child has accidentally ingested the medicine, contact a doctor, hospital or the Poison Information Center (tel. 112) for assessment of the risk and advice. Nicotine doses that are tolerated by adult smokers undergoing treatment can cause severe symptoms of intoxication and potentially fatal outcome in children.

Symptoms of overdose include nausea, vomiting, increased salivation, abdominal pain, diarrhea, sweating, headache, dizziness, hearing change, and a pronounced feeling of weakness. At high doses, these symptoms may be followed by low blood pressure, weak and irregular pulse, difficulty breathing, extreme fatigue, circulatory collapse, and general seizures.

4. Possible side effects

Symptoms associated with quitting smoking (withdrawal symptoms)

Some of the side effects that you experience when you quit smoking may be withdrawal symptoms, which occur due to reduced nicotine intake.

These symptoms include:

- Irritation, aggression, impatience or frustration
- Anxiety, restlessness, or difficulty concentrating
- Waking up at night or sleep disturbances
- Increased appetite or weight gain
- Depression
- Craving
- Lowered heart rate
- Bleeding gums or mouth ulcers
- Dizziness or a feeling as if about to faint
- Cough, sore throat, blocked or runny nose
- Constipation

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

Nicorette can cause the same side effects as nicotine given in other ways. The side effects generally depend on the size of the dose you are taking.

Local, mild skin reactions may occur during the first few weeks of treatment. The best way to avoid the discomfort is to switch places for the patch every day, for example between the right and left arm and the right and left hips

If you notice that you have any of the following serious and rare side effects, stop taking Nicorette and seek medical attention immediately.

Symptoms of angioedema (may affect up to 1 in 1,000 users):

- swelling of the face, tongue, or throat
- difficulty swallowing
- hives, skin rash, and difficulty breathing

Very common side effects (may affect more than 1 in 10 users):

- Itch

Common side effects (may affect up to 1 in 10 users):

- Skin rash (including hives)
- Headache
- Nausea, vomiting

Uncommon side effects (may affect up to 1 in 100 users):

- Hypersensitivity (allergy)
- Heart palpitations (an abnormal experience of your heartbeat), increased heart rate

- Stinging sensation
- Redness of the skin (flushing), high blood pressure
- Difficulty breathing (dyspnea)
- Increased sweating
- Muscle pain in the vicinity of the patch
- Weakness, chest discomfort and pain, malaise, fatigue, application site reactions

Rare side effects (may affect up to 1 in 1,000 users):

- Allergic reaction with swelling of the face and mouth (angioedema or anaphylaxis)
- Redness of the skin
- Pain in the arm or leg
- Stomach abnormalities
- Abnormal heart rhythm (atrial fibrillation)

Reported (affects an unknown number of users):

- Epileptic attack (may involve seizures)

Reporting of adverse reactions

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Medical Products
Agency Box 26
751 03 Uppsala
Website: www.lakemedelsverket.se

5. How to store Nicorette Novum

Keep this medicine out of the sight and reach of children. Do not store above 25°C.
Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

The used patch must be folded together with the sticky side inwards and stored safely so that children cannot get access to the patch. Return used patches to the pharmacy. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nicorette Novum transdermal patch contains

Nicorette Novum transdermal patches are available in three strengths that deliver a total of 10, 15 and 25 mg of nicotine respectively over 16 hours of use.

Nicorette Novum transdermal patch 10 mg/16 h contains 15.8 mg nicotine
Nicorette Novum transdermal patch 15 mg/16 hours contains 23.6 mg
nicotine Nicorette Novum transdermal patch 25 mg/16 hours contains 39.4
mg nicotine

The other ingredients are:

Backing layer with imprint: Polyethyleneterephthalate film (PET), printing ink (blending varnish, printing ink brown, retarder, hardener).

Nicotine layer: medium chain triglycerides, basic butylated methacrylate copolymer

Acrylate matrix: acrylic adhesive (solution), potassium hydroxide, croscarmellose sodium, aluminium acetylacetonate

Protective film: polyethyleneterephthalate (PET) film (aluminium coated on one side and siliconized on both sides)

What Nicorette Novum transdermal patch looks like and contents of the pack

Appearance:

Nicorette Novum transdermal patch is a semi-transparent patch. The patch is marked with Nicorette in light brown print.

Patch size:

10 mg/16 h: Area 9 cm²measure: 27.7 x 33.2 mm

15 mg/16 h: Area 13.5 cm²measure: 33.2 x 41.3 mm

25 mg/16 h: Area 22.5 cm²measure: 43 x 53 mm

Presentations:

10 mg/16 h: 7 and 14 patches

15 mg/16 h: 7, 14, 21 and 28 patches

25 mg/16 hours: 7, 14, 21 and 28 patches

Not all pack sizes may be marketed.

Marketing authorization holder:

McNeil Sweden AB, Solna

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