

## Package leaflet: information for the user

Nicorette® Invisipatch 10 mg, patch for transdermal use  
Nicorette® Invisipatch 15 mg, patch for transdermal use  
Nicorette® Invisipatch 25 mg, patch for transdermal use

### Nicotine

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Always use 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.
- Do you have any questions? Contact your pharmacist.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.
- Are you still having difficulty quitting smoking after 6 months? Then contact your doctor.

#### Contents of this leaflet

1. What is Nicorette Invisipatch and what is it used for?
2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

#### 1. What is Nicorette Invisipatch and what is it used for?

Nicorette Invisipatch is a patch for application on intact skin, also known as a patch for transdermal use.

The patch contains nicotine. When the patch is applied, the nicotine is slowly released and absorbed through the skin, but without reaching the high and rapid nicotine concentration in the blood as during smoking a cigarette. The patch is designed to release nicotine during the period when one is accustomed to smoking; thus only during the day (for about 16 hours). This nicotine is enough to reduce the urge to smoke. Unlike tobacco smoke, Nicorette Invisipatch does not contain harmful tar or carbon monoxide.

The nicotine in Nicorette Invisipatch belongs to the group of withdrawal aids. Nicorette Invisipatch is used to relieve the strong craving for nicotine that people may experience when quitting smoking.

#### 2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- You have a severe heart condition (a recent heart attack (in the past 3 months); arrhythmias; a constricting, painful feeling in the chest (angina pectoris); or a so-called Prinzmetal angina).
- You have recently had a brain hemorrhage (stroke).
- You suffer from a generalized chronic skin condition such as psoriasis, chronic dermatitis, or hives: then it is better to use another form of nicotine-containing oromucosal product and not the patches for transdermal use.

Nicorette is not intended for children under 18 years or for people who are not accustomed to smoking regularly. During treatment with Nicorette, transdermal patches, you should not continue to smoke.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

It is in the patient's interest that the treatment is combined with other activities (including sports) to facilitate smoking cessation.

Your doctor should evaluate whether you may use Nicorette:

- if you have or have had a recent heart attack, unstable or worsening angina pectoris, including Prinzmetal's angina, severe arrhythmias, uncontrolled hypertension, or a recent stroke: preferably you should quit smoking under guidance without nicotine replacement therapy. The patch should be used with caution if you suffer from heart or blood vessel diseases (e.g., high blood pressure, angina, heart failure, vascular spasms) or conditions of the blood vessels in the brain.
- if you have diabetes: then your blood sugar level should be monitored more closely.
- if you have kidney and liver disease: there is a chance of an increase in side effects.
- if you have a tumor of the adrenal glands (pheochromocytoma) or uncontrolled hyperthyroidism.
- if you have gastrointestinal disorders (inflammation of the esophagus, stomach or duodenal ulcer): nicotine may worsen your symptoms.
- if you have had epilepsy or seizures in the past.

The patch should be removed prior to undergoing MRI procedures (magnetic resonance imaging) to prevent the risk of burns.

Nicotine replacement therapy poses fewer risks with the aforementioned conditions than smoking itself. In any case, continuing to smoke is certainly more detrimental if you have cardiovascular disease.

Consult your doctor if any of the above warnings apply to you, or have applied in the past.

Children and adolescents up to 18 years

Nicorette should not be administered to persons under 18 years without a doctor's prescription. Danger to children: nicotine doses tolerated by smokers (adults and adolescents) can cause severe poisoning symptoms in children and be fatal. Nicotine products should not be stored in places where they can be handled or ingested by children.

Are you using any other medicines?

Are you using any other medicines besides Nicorette Invisipatch, have you done so recently, or are you going to do so soon? Then tell your doctor or pharmacist. This also applies to medicines you can obtain without a prescription.

The dose of some medicines needs to be adjusted when quitting smoking.

What should you pay attention to with food and drink?

No particularities.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

It is very important to stop smoking during pregnancy because it can negatively affect your baby's development. It can also lead to premature birth or stillbirth. It is best if you can quit smoking without using nicotine-containing medications. If you cannot, this medicine should only be used after consulting with a healthcare professional monitoring your pregnancy. For women who wish to become pregnant, it is safest not to smoke or use nicotine replacement therapy.

Breastfeeding

This medicine should be avoided during breastfeeding because nicotine is found in breast milk and can affect your child. If your doctor has recommended the use of a nicotine-containing product, it should be used as soon as possible after breastfeeding and not during the 2 hours preceding breastfeeding. Using another form of Nicorette is preferred over patches.

Fertility

Smoking increases the risk of infertility in both women and men. The effect of nicotine on fertility is unknown.

Driving and using machines

Nicorette has no or negligible influence on the ability to drive and use machines. At the start of treatment or with excessive use, dizziness may occur.

### 3. How to use this medicine?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

How should you use Nicorette Invisipatch?

Nicorette Invisipatch should be applied to clean, dry, intact, and hairless skin, such as on a hip, upper arm, or chest. The patch application site should be alternated daily. Never apply the patch to the same site on two consecutive days.

1. Wash your hands before applying the patch.
2. Open the sachet laterally as indicated, using scissors. Then choose a clean, dry, intact, and hairless site, such as a hip, upper arm, or chest.
3. Remove one part of the aluminum foil as far as possible.

Avoid touching the adhesive surface of the patch with your fingers as much as possible.

4. Carefully apply the adhesive side of the patch to the skin and remove the rest of the protective foil.
5. Press the patch firmly onto the skin with your palm or fingertips.
6. Rub your fingers firmly along the edge of the patch to ensure it adheres well.

After removal, the patch should be folded in half with the adhesive side inward, and placed back in the opened sachet or wrapped in aluminum foil. The used patch should then be carefully disposed of, out of reach of children and pets. A used patch should never be flushed down the toilet.

The patch will normally remain adhered when taking a bath or shower and during swimming; if it does come off, dry the skin thoroughly and apply a new patch.

How many patches can you use and for how long?

Use a new patch every day: apply in the morning upon waking and remove in the evening before sleeping.

You should maintain this for at least 3 months. Advice and support generally improve the chances of success.

Which type of patch is best for you to use?

#### Monotherapy

Heavy smokers (you smoke 15 cigarettes or more per day):

Start the treatment with Nicorette Invisipatch 25 mg for 8 weeks.

Afterwards, you should gradually reduce. You can do this by switching to progressively lighter types: first Nicorette Invisipatch 15 mg for 2 weeks, then Nicorette Invisipatch 10 mg for another 2 weeks.

Light smokers (you smoke less than 15 cigarettes per day):

Start the treatment with Nicorette Invisipatch 15 mg for 8 weeks. Then switch to Nicorette Invisipatch 10 mg for another 4 weeks.

| Heavy smokers ( $\geq 15$ cigarettes/day) |                             |               | Light smokers ( $< 15$ cigarettes/day) |               |  |
|---|-----------------------------|---------------|--|---------------|--|
| Dosage                                    | Duration                    |               | Dosage                                 | Duration      |  |
| Step 1                                    | Nicorette Invisipatch 25 mg | First 8 weeks |  |               |  |
| Step 2                                    | Nicorette Invisipatch 15 mg | Next 2 weeks  | Step 1 Nicorette Invisipatch 15 mg     | Last 4 weeks  |  |
| Step 3                                    | Nicorette Invisipatch 10 mg | Last 2 weeks  | Step 2 Nicorette Invisipatch 10 mg     | First 8 weeks |  |

#### Combination therapy

Heavy smokers, smokers who experience a sudden, uncontrollable urge to smoke (also known as craving), or smokers for whom treatment with a single form of nicotine replacement therapy has not been successful, can use Nicorette Invisipatch in combination with an oromucosal form of Nicorette with rapid release, for quick relief of cravings. This can be one of the following forms: Nicorette gum of 2 mg, Inhaler of 10 mg or 15 mg or 1 mg/spray, spray for oromucosal use.

Follow the same dosage recommendations as for monotherapy for the patch. For the correct use of the additional oromucosal form, consult the respective leaflet. If the chosen oromucosal product is not satisfactory, it can be switched to another oromucosal formulation when a new patch is applied. For combination therapy, smokers are advised to use only one oromucosal product alongside the patch, and not multiple at the same time.

Use in children and adolescents up to 18 years

Nicorette should not be administered to individuals under 18 years without a doctor's prescription.

Have you used too much of this medicine?

Symptoms of overdose

Overdose can occur if you use multiple patches at the same time, or if you are not accustomed to nicotine. Overdose can also occur if, in addition to the Nicorette patch, you use other forms of nicotine, such as continuing to smoke. If someone, however unlikely, swallows the patch, the risk remains limited because the nicotine is released very slowly.

Symptoms of overdose include: nausea, vomiting, salivation, abdominal pain, diarrhea, sweating, headache, dizziness, hearing disorders, and clear signs of weakness. In extreme cases, these can be followed by low blood pressure, a weak irregular pulse, breathing difficulties, general weakness, circulatory collapse (fainting due to disturbances in blood circulation), and convulsions.

The acute minimal lethal oral nicotine dose in humans is estimated at 40 to 60 mg.

The usual dosage of nicotine tolerated by adult smokers during therapy can cause severe poisoning symptoms in children and can be fatal.

If you have used too much Nicorette, stop nicotine intake immediately and contact your doctor or pharmacist immediately, especially if it concerns a child where nicotine poisoning is suspected.

Information for the doctor: treatment in case of overdose

Nicotine intake must be stopped immediately and a doctor should be called. The patient should be treated symptomatically.

Have you forgotten to use this medicine?

If you forget to apply a patch, you should do so as soon as you remember. Remove the patch at bedtime.

If you stop using this medicine

If you stop using the patch too early while you want to quit smoking, the chance of you starting to smoke again increases.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can also have side effects. Not everyone experiences them.

When using Nicorette Invisipatch, local side effects may occur in the form of mild local skin reactions. These occurred in about 20% of the users during the first weeks of treatment. Most of the reported side effects occur during the first 3-4 weeks of treatment and are mainly dose-dependent.

This medicine can cause the same side effects as other forms of nicotine. The side effects generally depend on the dose you take.

In combined nicotine replacement therapy, local side effects may occur as a result of the additional oromucosal product.

For some smokers, it is difficult to reduce their nicotine dependence. Prolonged use of nicotine replacement may occur as a result.

Effects caused by quitting smoking (nicotine withdrawal) Some of the side effects you experience when quitting smoking may be withdrawal symptoms due to reduced nicotine intake.

These effects include:

- Irritability, aggression, impatience, or frustration
- Feeling anxious, restlessness, or concentration problems
- Night waking or sleep disturbances
- Increased appetite or weight gain
- Feeling depressed
- Craving to smoke
- Slowed heart rate
- Bleeding gums or painful sores in the mouth (canker sores)
- Dizziness or a light-headed feeling
- Coughing, sore throat, blocked nose or runny nose
- Constipation

If you experience any of the following serious rare side effects, stop using this medicine and contact a doctor immediately (symptoms of angioedema):

- Swelling of the face, tongue or throat
- Difficulty swallowing
- Skin rash with severe itching and bumps and difficulty breathing

The following side effects may occur very frequently (in more than 1 in 10 users): itching, nausea, headache.

The following side effects may occur frequently (in less than 1 in 10 users): hypersensitivity, tingling, vomiting, fatigue, skin rash, hives.

The following side effects may occur occasionally (in less than 1 in 100 users): palpitations, increased heart rate, reaction at the administration site, general body weakness, unpleasant feeling and chest pain, discomfort, muscle pain, abnormal dreams with formulations administered during the night, shortness of breath, sweating, flushing, increased blood pressure.

The frequency of the following side effects is not known: gastrointestinal discomfort and/or pain, severe hypersensitivity reaction, pain in the limbs, itchy edema of skin or mucous membranes, skin redness, seizures, a rapid and irregular heartbeat (atrial fibrillation).

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via:

The Netherlands Pharmacovigilance Centre (website: [www.lareb.nl](http://www.lareb.nl)).

By reporting side effects, you help us obtain more information about the safety of this medicine.

#### 5. How do you store this medicine?

Store below 25°C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the packaging after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

Ensure safe disposal of the patch after use, out of the reach of children and pets.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal ensures they are destroyed correctly and do not enter the environment.

#### 6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is nicotine. Each patch contains 1.75 mg nicotine per cm<sup>2</sup>. Nicorette Invisipatch 10 mg has a size of 9.0 cm<sup>2</sup>. Nicorette Invisipatch 15 mg has a size of 13.5 cm<sup>2</sup>. Nicorette Invisipatch 25 mg has a size of 22.5 cm<sup>2</sup>.

The other substances in this medicine are medium chain triglycerides, basic butylated methacrylate copolymer, polyethylene terephthalate film (PET), acrylate copolymer, potassium hydroxide (E525), sodium croscarmellose (E468), aluminum acetylacetonate and polyethylene terephthalate film (PET), siliconized and coated on one side with aluminum, printing ink.

What does Nicorette Invisipatch look like and what is in a package?

Nicorette Invisipatch is a semi-transparent patch for nicotine administration through the skin.

Nicorette Invisipatch 10 mg is available in packages of 7 and 14 patches.

Nicorette Invisipatch 15 mg and 25 mg are available in packages of 7, 14, and 28 patches.

It is possible that not all mentioned package sizes are marketed.

Each patch is packed in a heat-sealed laminate sachet.

Marketing authorization holder

Kenvue Netherlands B.V.  
Stadsplateau 27  
3521 AZ Utrecht

Manufacturer

LTS Lohmann Therapie-Systeme AG, Lohmannstraße 2, 56626 Andernach, Germany

Marketing authorization numbers

Nicorette Invisipatch 10 mg: RVG 34968

Nicorette Invisipatch 15 mg: RVG 34969

Nicorette Invisipatch 25 mg: RVG 34970

This leaflet was last approved in November 2025.

Transtoyou