

Package leaflet: Information for the user

NiQuitin Clear 7 mg/24 hours transdermal patch
NiQuitin Clear 14 mg/24 hours transdermal patch
NiQuitin Clear 21 mg/24 hours transdermal patch
Nicotine

Read all of this 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.
- 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 you have not been able to stop smoking after 10 weeks of treatment with NiQuitin Clear

What is in this leaflet:

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

1. What NiQuitin Clear is and what it is used for

NiQuitin Clear is used in stopping smoking. The active substance in NiQuitin Clear is nicotine. It acts as a temporary aid so that you can stop smoking. It works to alleviate nicotine withdrawal symptoms as a result of stopping smoking. This type of treatment is called Nicotine Replacement Therapy or NRT. If possible, you should use NiQuitin Clear as part of a smoking cessation programme.

NiQuitin Clear are transparent, rectangular sustained release patches, which releases a uniform amount of nicotine through the skin into the body over a period of 24 hours.

NiQuitin Clear is less harmful than smoking, as NiQuitin Clear does not contain the tar and carbon monoxide of cigarette smoke.

2. What you need to know before using NiQuitin Clear

Do not use NiQuitin Clear:

- if you are allergic to nicotine or any of the other ingredients of this medicine (listed in section 6).
- if you are a non-smoker, occasional smoker or a child under the age of 12 years.

NiQuitin Clear should only be used by adolescents (aged 12-17 years) if recommended by a doctor. Adolescents should not use NiQuitin patches in combination with oral forms of NiQuitin such as lozenges, mini-lozenges or gums.

Warnings and precautions

Talk with your doctor or pharmacist before using NiQuitin Clear:

- if you have high blood pressure which is not being controlled by medicines.
 - if you have any cardiovascular disease, for example angina pectoris or heart failure.
 - if you have cerebrovascular disease (conditions of impaired blood flow in the brain).
 - if you are in hospital because of a heart attack, heart rhythm problems or a stroke. Tell the doctor that you are taking NiQuitin Clear.
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- if you have inflammation of the skin (eczema), since you may get a reaction to the patch.
 - if you have diabetes, since the blood glucose levels may be more variable when stopping smoking. The doctor may tell you to monitor your blood sugar levels more often than usual when you start using NiQuitin Clear.
 - if you have liver or kidney problems, because you may be more likely to get side effects.
 - if you have an uncontrolled and overactive thyroid or have been diagnosed with a tumour of the adrenal gland (pheochromocytoma).
 - if you have ever experienced seizures.
 - if you have inflammation in the mouth, throat or esophagus, or gastritis or peptic ulcer. Nicotine replacement therapy may worsen those symptoms

If you get skin redness, swelling or rash you should stop using the patch and consult your doctor or pharmacist.

Some people worry that after stopping smoking, they may become dependent on nicotine replacement therapy instead. This is unusual, and if it did happen, it is less harmful than continuing to smoke. It is also an easier habit to break.

Children

The amount of nicotine tolerated by adult smokers can cause symptoms of poisoning and even be life-threatening if NiQuitin Clear is used or swallowed by children. Even used NiQuitin Clear patches contain enough residual nicotine to be harmful to children.

Therefore keep NiQuitin Clear patches out of the reach of children and dispose of used patches in a child-safe manner, see section 5. How to store NiQuitin Clear.

Other medicines and NiQuitin Clear

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Adjustment of the dose by your doctor may be required when taking the following medicines: Asthma medicine (theophylline), antidepressants (imipramine, clomipramine), analgesics (pentazocine, phenacetin), anti-inflammatory agents (phenylbutazone), agents for dementia (Alzheimer's disease) (tacrine) or antidiabetics (insulin) and medicines for irregular or fast heart beats (adenosine).

Stopping smoking, with or without NiQuitin Clear, can alter the reaction to other medicines being taken at the same time.

Pregnancy and breast-feeding

Pregnancy

It is very important to stop smoking during pregnancy because smoking can result in poor growth of your baby. Smoking can also lead to premature births and even stillbirths. It is best if you can give up smoking without the use of medicines containing nicotine. If you cannot manage this, NiQuitin clear should only be used after consulting a healthcare professional.

Breast-feeding

NiQuitin clear should be avoided during breast-feeding as nicotine is found in breast milk and may affect your child. Consult a healthcare professional before you start using NiQuitin clear during breast-feeding.

Use of NiQuitin Clear patches in combination with oral forms of nicotine such as lozenges, mini lozenges or gums is not recommended during pregnancy or breastfeeding unless recommended by a healthcare professional.

Driving and using machines

As far as is known, NiQuitin Clear has no effect on the ability to drive or use machines.

3. How to use NiQuitin Clear

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.

It is important that you stop smoking completely when you stop smoking with the aid of NiQuitin Clear patches. In some instances, it may be beneficial to use oral nicotine replacement therapy forms (such as lozenges or gums) in combination with NiQuitin Clear patches – to help control sudden cravings.

Dosage

For smokers who smoke more than 10 cigarettes a day it is recommended that the following dosing schedule be observed:

Dose	Duration
<i>Step 1</i> NiQuitin Clear 21 mg/24 hours	1 patch every day for the <u>first 6 weeks</u> , then
<i>Step 2</i> NiQuitin Clear 14 mg/24 hours	1 patch every day for the <u>next 2 weeks</u> , then
<i>Step 3</i> NiQuitin Clear 7 mg/24 hours	1 patch every day for the <u>last 2 weeks</u> .

Light smokers (those smoking fewer than 10 cigarettes a day) are advised to observe the following dosing schedule:

Dose	Duration
<i>Step 2</i> NiQuitin Clear 14 mg/24 hours	1 patch every day for the <u>first 6 weeks</u> , then
<i>Step 3</i> NiQuitin Clear 7 mg/24 hours	1 patch every day for the <u>last 2 weeks</u> .

Patients using NiQuitin Clear 21 mg who experience excessive side effects that do not resolve within a few days should transfer to the following dosing schedule:

Dose	Duration
<i>Step 2</i> NiQuitin Clear 14 mg/24 hours	1 patch every day for the rest <u>of the first 6 weeks</u> , then
<i>Step 3</i> NiQuitin Clear 7 mg/24 hours	1 patch every day for the <u>last 2 weeks</u> .

Combination therapy

If you experience strong cravings to smoke, combination therapy of transdermal patches and oral forms of nicotine provide a better chance of quitting than patches alone.

Read the patient information leaflet for NiQuitin Mini 1.5mg lozenge/NiQuitin 2mg lozenge/NiQuitin 2mg gum before use.

The recommended dosage for NiQuitin Clear patches follows the same ‘Step’ process as outlined above. In addition to the patch you can take either NiQuitin Mini 1.5mg lozenge, NiQuitin 2mg lozenge or NiQuitin 2mg gum whenever you experience a sudden craving - on average 5-6 pieces per day. Do not exceed 15 pieces in 24 hours and use only one oral NiQuitin product in combination with NiQuitin Clear patch.

You should continue to use NiQuitin Mini 1.5mg lozenge/NiQuitin 2mg lozenge/NiQuitin 2mg gum for 2 - 3 months, then begin to reduce use gradually as you experience less nicotine cravings. When daily use is reduced to 1-2 doses, use should be stopped.

For smokers who smoke more than 10 cigarettes a day		
Period	Patches	NiQuitin Mini 1.5mg lozenge/ NiQuitin 2mg lozenge/ NiQuitin 2mg gum
Step 1: 6 weeks	NiQuitin Clear 21 mg / 24 hours	5 to 6 pieces per day
Step 2: 2 weeks	NiQuitin Clear 14 mg / 24 hours	Continue to use lozenges/gums, when necessary
Step 3: 2 weeks	NiQuitin Clear 7 mg / 24 hours	
After 10 weeks	Stop using NiQuitin Clear patches	Reduce the number of lozenges/gums gradually. When daily use is reduced to 1-2 pieces, treatment should be stopped.
Light smokers (those smoking fewer than 10 cigarettes a day)		
Period	Patches	NiQuitin Mini 1.5mg lozenge/ NiQuitin 2mg lozenge/ NiQuitin 2mg gum
Step 2: 6 weeks	NiQuitin Clear 14 mg / 24 hours	5 to 6 pieces per day
Step 3: 2 weeks	NiQuitin Clear 7 mg / 24 hours	Continue to use lozenges/gums, when necessary
After 8 weeks	Stop using NiQuitin Clear patches	Reduce the number of lozenges/gums gradually. When daily use is reduced to 1-2 pieces, treatment should be stopped.

For information about how long you can use NiQuitin Mini 1.5mg lozenge/NiQuitin 2mg lozenge/NiQuitin 2mg gum, please refer to the patient information leaflet for the respective product.

Consult a doctor if the symptoms persist. If you feel the need to use NiQuitin Mini 1.5 mg lozenge/NiQuitin 2mg lozenge/NiQuitin 2mg gum for longer than 9 months in total, you should ask a healthcare professional for advice.

Instructions for use

- NiQuitin Clear patches should be affixed once a day.
- Affix a new NiQuitin Clear patch at the same time each day, preferably soon after waking, to a clean, dry, hairless area of skin. Avoid areas with skinfolds (such as over a joint) or when the skin creases when you move.
- Do not affix NiQuitin Clear patches to areas of skin that are red, irritated or damaged.
- NiQuitin Clear patches should be worn continuously, for 24 hours. If desired, patches can be removed before going to sleep. However, 24-hour use is recommended for optimum effect against the urge to smoke in the morning.
- A patch should not be worn for longer than 24 hours.
- After 24 hours the used patch should be removed and a new patch affixed to a different area of skin.
- When you have removed a patch, fold it in half with the adhesive side inwards and place it in the empty sachet of the patch that is to be newly applied. Dispose of the sachet with the used patch inside with care, keep out of the reach of children.
- An area of skin used for a patch should not be used again for a new patch for at least seven days.
- Do not use several patches at the same time.

How do you affix NiQuitin Clear?

- The NiQuitin Clear patch should be affixed immediately after opening the sachet.
- The patch should be kept sealed in its protective pouch until ready to use.
- Cut the sachet open along the dotted line or fold the sachet over this line and tear it open, being careful not to damage the patch.
- Carefully remove the patch from the sachet. A transparent protective layer covers the adhesive side of the patch – the side that will be put on your skin.
- Remove one half of the protective layer from the middle, with the adhesive layer facing you. Hold the patch by the outermost edge (touching the adhesive layer as little as possible) and remove the other half of the protective layer.
- Apply the adhesive layer of the NiQuitin Clear patch straightaway to your skin. Press the patch firmly to your skin with the palm of your hand for at least 10 seconds. Ensure that the patch sticks to the skin well, particularly along the edges.
- Avoid contact with eyes and nose when handling the patch.
- Always wash your hands just with water after handling the NiQuitin Clear patch. (Soap can increase the absorption of nicotine).

If used correctly, water is not harmful to NiQuitin Clear patches. You can bathe, swim or shower for short periods whilst using NiQuitin Clear patches.

For how long may you use NiQuitin Clear?

- For optimum results the full 10-week course of treatment (8 weeks for light smokers or patients using a lower strength, as described above) should be completed.
- The treatment should not last for longer than 10 consecutive weeks.
- NiQuitin Clear users who do not succeed in quitting or who resume smoking can however start a new course of treatment at a later date.

- For information about how long you can use NiQuitin Mini 1.5mg lozenge/NiQuitin 2mg lozenge/NiQuitin 2mg gum, please refer to the patient information leaflet that you have received for the respective product.

If you wear NiQuitin Clear for longer than you should

- Remove the patch immediately. Contact a doctor if symptoms of overdose are visible, if possible show the doctor the package or leaflet. Symptoms of overdose are: pallor, cold sweat, nausea, increased salivation, vomiting, abdominal pain, diarrhoea, headache, dizziness, impaired hearing and vision, shaking, mental confusion and weakness.
- The surface of the skin can be washed with water and dried. Do not use soap as it can increase the absorption of nicotine through the skin.
- After removing the patch, nicotine will still be released into the bloodstream for several hours due to storage of nicotine in the skin.
- If possible show the doctor the packet or this leaflet.

If you forget to use NiQuitin Clear or the patches falls off:

- Forgetting a dose does not have any adverse consequences. Nicotine values in the blood will fall, however, and this may cause protection against nicotine withdrawal symptoms to be temporarily less. You should continue with the stated dose as soon as possible.
- NiQuitin Clear patches generally adhere well. Should a patch nevertheless fall off, affix a new patch to a different area of clean, dry, hairless skin. Keep to the original times.

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.

Reactions at the site of application, including transient rash, itching, burning, tingling sensation, numbness, swelling, pain and rash are the most common side-effects of NiQuitin Clear. The majority of the skin reactions are not severe and quickly resolve after the patch has been removed. In the event of severe or persistent skin complaints, whether they are at the site where the patch was affixed or not, consult your doctor and stop using NiQuitin Clear.

Stop taking NiQuitin Clear and see a doctor immediately if you experience any of the following symptoms:

- Common: may affect up to 1 in 10 people:
 - Palpitations, an abnormal or fast heart beat
- Very rare side effects: may affect up to 1 in 10,000 people:
 - Severe allergic reaction, symptoms of which include sudden wheeziness or tightness of the chest, rash and feeling faint
- Not known: frequency cannot be estimated from the available data
 - Seizures

Other possible side effect that may occur:

- Very common: may affect more than 1 in 10 people:
 - sleep disorders including abnormal dreams and insomnia

- nausea
 - vomiting
 - headache
 - dizziness.
- Common: may affect up to 1 in 10 people:
 - nervousness
 - chest pain
 - pain in limb
 - pain
 - weakness
 - muscle pain
 - joint pain
 - increased sweating
 - indigestion
 - dry mouth
 - constipation
 - respiratory distress
 - pharyngitis
 - cough
 - shaking
 - diarrhoea
 - fatigue.
- Uncommon: may affect up to 1 in 100 people:
 - heart palpitations
 - Malaise
 - influenza-like illness
 - allergy.
- Very rare: may affect up to 1 in 10,000 people:
 - contact dermatitis.
 - Photosensitivity

These side-effects may, however, also be the result of stopping smoking.

Some people experience sleep disturbances, including vivid dreams. Since these can be due to the fact that you have stopped smoking rather than to the patch, you should continue to wear the patch for a day or two. If the symptoms persist, try removing the patch before you go to bed (after about 16 hours) and put a new one on when you wake up. If the patch is removed after 16 hours, it will however be less effective at suppressing the craving that many smokers experience on waking.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#)*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NiQuitin Clear

- Store below 30°C
- Keep this medicine out of sight and reach of children
- Do not use this medicine after the expiry date which is stated on the carton after “exp”. The expiry date refers to the last day of that month.
- Keep all patches in the carton, in their protective sachets, until you are ready to use one
- Do not use NiQuitin Clear from sachets which are damaged or open.

After removal, the patch should be folded in half, adhesive side innermost, and placed inside the opened sachet, or in a piece of aluminium foil. The used patch should then be disposed of with care.

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 protect the environment.

6. Contents of the pack and other information

What NiQuitin Clear contain:

- The active substance is nicotine
- The other ingredients are ethylene vinyl acetate copolymer, polyethylene terephthalate/ethylene vinyl acetate, polyethylene film, polyisobutylene and white printing ink (titanium dioxide, E 171).

NiQuitin Clear is available in three strengths:

Step 1: NiQuitin Clear 21 mg/24 hours; contains 114 mg nicotine and releases 21 mg nicotine over 24 hours.

Step 2: NiQuitin Clear 14 mg/24 hours; contains 78 mg nicotine and releases 14 mg nicotine over 24 hours.

Step 3: NiQuitin Clear 7 mg /24 hours; contains 36 mg nicotine and releases 7 mg nicotine over 24 hours.

What NiQuitin Clear look like and contents of the pack:

Each sustained released patch is rectangular and is comprised of a clear backing and a protective liner. Each patch is contained in a laminate sachet. There are 7, 14 or 21, 28 or 42 patches in a pack. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden: NiQuitin Clear Depotplåster 7 mg/24 timmar, 14mg/24 timmar, 21 mg/24 timmar

Netherlands: NiQuitin Clear 7 mg/24 uur, 14 mg/24uur, 21 mg/24 uur

This leaflet was last approved in 2021-04-30