

NiQuitin[®] CLEAR Patches

Nicotine

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use NiQuitin Clear patches carefully to get the best results from them.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask a healthcare professional (doctor, nurse, smoking cessation advisor or pharmacist).

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1. What NiQuitin Clear patches do

NiQuitin Clear patches are used to help people stop smoking. This type of treatment is called Nicotine Replacement Therapy or NRT.

It is the nicotine in cigarettes that can make you physically addicted to them.

- NiQuitin Clear patches help you to give up smoking by replacing some of the nicotine you get from cigarettes.
- The patches provide a steady amount of nicotine to your body, generally at a lower level than from cigarettes.
- This nicotine relieves some of the unpleasant symptoms that smokers may have when they try to give up. These include feeling ill or irritable.
- The nicotine can also reduce your cravings for a cigarette and help you to resist the urge to smoke.

NiQuitin Clear patches do not have the health dangers of tobacco. This is because they do not contain the tar, carbon monoxide or other toxins in cigarette smoke. Some people worry that after stopping smoking they may become dependent on nicotine patches instead. This is very rare and if it did happen, it is less harmful than continuing to smoke. It is also an easier habit to break.

Your chances of stopping smoking will be improved if you take part in a support programme. These "stop smoking programmes" are known as behavioural support. Please see the insert in this pack for more details.

2. Check before you use NiQuitin Clear patches

 **Do not use NiQuitin Clear patches:**

- if you have ever had an **allergic reaction** to nicotine or any of the other ingredients (listed in Section 6)
- if you are a **non-smoker** or an **occasional smoker**
- if you are **under 12 years**. The levels of nicotine in NRT are suitable for people who are giving up smoking but not for children under 12. Children are more susceptible to the effects of nicotine and it could cause severe toxicity which can be fatal.

There are no health benefits to smoking. It is always better to give up smoking. Using NRT like NiQuitin Clear patches can help. In general, any possible side effects associated with NRT are far outweighed by the well established dangers of continuing to smoke.

 **Take special care with NiQuitin Clear patches**

Get help and advice from a healthcare professional:

- if you are in **hospital** because you have had a **heart attack, severe heart rhythm disturbances** or a **stroke**. Try to quit smoking without NRT unless your doctor tells you to use it. Once you are discharged from hospital, you can use NRT as normal.
- if you have **diabetes** you should monitor your blood sugar levels more often than usual when starting NiQuitin Clear patches as you may find your medication requirements change.
- if you have **serious liver or kidney problems** because you may be more likely to get side effects.
- if you have **uncontrolled overactive thyroid gland** or an **adrenal gland tumour** (phaeochromocytoma) because nicotine may make your symptoms worse.

- if you have **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.
- if you have **allergic eczema or dermatitis** you may get a reaction to the patch.

 **If you are taking other medicines**

Stopping smoking may alter the effect of other medicines you may be taking. If you have any questions or concerns about this, talk to a healthcare professional.

 **Pregnancy and breastfeeding**

If you are **pregnant or breastfeeding** it is best if you can give up smoking without the use of NRT. However, it is better to stop smoking using NRT than to continue smoking.

Smoking during pregnancy has risks for the baby. These include poor growth before birth, premature birth or stillbirth. Stopping smoking is the best way to improve both your health and that of your baby and the earlier you stop smoking the better.

Ideally, if you are pregnant you should stop smoking without using NRT. However, if you have tried and this hasn't worked, NRT may be recommended to help you stop: it is better for your developing baby than if you carry on smoking. The decision to use NRT should be made as early on in your pregnancy as possible.

- Aim to use NRT for only 2 to 3 months. Remember, the most important thing is to stop smoking.
- NRT gum or lozenges may be preferable to nicotine patches as you do not get nicotine all the time. However, patches may be preferred if you have nausea or sickness.
- If you use NiQuitin Clear patches, remove the patch before going to bed.

If you are **breastfeeding** tobacco smoke causes breathing difficulties and other problems in babies and children. If you need to use NRT, the amount of nicotine your baby may get is smaller and less harmful than breathing in second-hand smoke.

- It is best to use NRT products that are taken to control cravings as they happen such as gum or lozenges, rather than patches.
- It is better to breastfeed just before you take the product – this helps your baby to get the smallest amount of nicotine possible.

3. How to use NiQuitin Clear patches

 **Adults and young people aged 12 years and over:**

It is important that you make every effort to stop smoking completely. If you do smoke a cigarette while you are using NRT, continue your quit attempt but talking to a healthcare professional may help.

The 10 week treatment course (8 weeks for light smokers or patients who have reduced strength), should be completed in full. Treatment may be continued beyond 10 weeks if you need to use them to stay cigarette free.

Adults aged 18 years and over: Do not use the patches beyond 9 months without talking to a healthcare professional.

Children aged 12 -18 years: Do not use the patches beyond 3 months without talking to a healthcare professional.

 **If you smoke 10 or more cigarettes a day, start with Step 1 and use the following step down programme:**

Weeks 1 to 6	Step 1	NiQuitin Clear 21 mg
Weeks 7 to 8	Step 2	NiQuitin Clear 14 mg
Weeks 9 to 10	Step 3	NiQuitin Clear 7 mg

 **If you smoke less than 10 cigarettes a day, then start with Step 2 and use the following step down programme:**

Weeks 1 to 6	Step 2	NiQuitin Clear 14 mg
Weeks 7 to 8	Step 3	NiQuitin Clear 7 mg

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As your body adjusts to not smoking, you are able to reduce the strength of patches used until you no longer need to use them. This step-down programme allows you to gradually overcome your body's need for nicotine.

To increase your chances of success, complete the step down programme in full and follow a stop smoking **behavioural support programme** - see the insert in this pack for more details.



• **Do not use more than the recommended dose.**

- If you feel you need to use the patches for longer than 9 months (3 months for 12-17 year olds) you should talk to a healthcare professional.
- If you are worried that you may start smoking again or are finding it difficult to stop using NRT 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 NRT.

How to apply the patches

It is important to choose a clean, dry and hairless area of skin on which to position the patch, to make sure that it sticks properly. Avoid areas where the skin creases (such as over a joint), or where the skin folds when you move. Also avoid skin which is red, broken or irritated.

- Do not remove the patch from its sealed protective sachet until you are ready to use it.
- Cut open the sachet along the dotted line, taking care not to damage the patch inside.
- Take out the patch carefully. A clear, protective liner covers the sticky side of the patch – the side that will be put on your skin.
- With the sticky side facing you, pull half the liner away from the patch starting at the middle. Hold the patch at the outside edge (touch the sticky side as little as possible), and pull off the other half of the protective liner.
- Immediately apply the sticky side of the patch to your skin. Press the patch firmly on to your skin with the palm of your hand for at least 10 seconds. Make sure it sticks well to the skin, especially round the edges.
- When applying the patch, avoid touching the eyes and nose. When you have finished, always wash your hands with water only. Do not use soap which may increase nicotine absorption.
- Water will not harm the patch if it has been applied properly. You can bathe, swim or shower for short periods while you are wearing the patch.

How to change your patches

- Apply a new patch once a day, preferably soon after waking.
- Leave each patch in place for 24 hours (remove at bedtime if you are pregnant).
- Always choose a different area of skin on which to place the new patch.
- Do not reuse the same skin site for at least 7 days.
- When you take off a patch, fold it in half with the sticky side inwards and place it in the sachet from which you have just taken your new patch.
- Throw the sachet containing the used patch away carefully, making sure it is out of the reach of children or pets.

NiQuitin Clear patches generally stick well to most people's skin. However, a patch may occasionally come off. If your patch falls off during the day, put on a new patch, making sure you choose a different non-hairy skin site that is clean and dry. Then go on as before. If you wish, the patch can be removed before you go to bed (after about 16 hours) and a new one put on when you wake up. However, removing the patch after 16 hours will reduce its effectiveness in relieving the urge to smoke felt by some smokers on waking.

If you forget to change your patch at the usual time, change it as soon as you remember then go on as before.

If you use too many patches

If you apply too many patches, you may start to feel sick, dizzy and unwell. Remove all patches and wash and dry the skin with water only (no soap). Contact your doctor or casualty department immediately and, if possible, show them the packet or this leaflet.

The patches are **not suitable for children under 12 years or non-smokers**. They may develop signs of nicotine overdose including headache, sickness, stomach pains and diarrhoea. If a child has stuck a patch on themselves or eaten one, remove any patches from their skin and wash and dry with water only (no soap). Contact your doctor or casualty department immediately and, if possible, show them the packet or this leaflet.

4. Possible side effects

Like all medicines, the nicotine in NRT products can have side effects. They are similar to those you might get from the nicotine in cigarettes, and are more likely the more nicotine you take, but not everybody gets them.

Stopping smoking itself can cause some symptoms such as feeling weak, tired, depressed, irritable, nervous, restless, anxious, drowsy, dizzy, unable to concentrate, headache, sleep disturbance/night-time awakening, cough, flu-like symptoms and changes in mood.

Other side effects may include:

- Severe reactions at the sticking site.
- Stop using the patch and tell a healthcare professional if you get this.**

- Increased heart rate.
- Remove the patch and reduce the dose if you get this.**

- Abnormal dreams, trembling, palpitations (feeling your heart beat).
- Shortness of breath.
- Feeling or being sick, indigestion, stomach pain, diarrhoea or constipation.
- Sweating.
- Dry mouth.
- Joint, muscle, chest and limb pains.
- Tiredness and feeling unwell.
- Slight redness and itching, burning and tingling of the skin where a patch has been. This usually disappears within a day.

Tell a healthcare professional if you get any of these.

If you do get any side effects, even those not mentioned in this leaflet, tell a healthcare professional.

5. How to store NiQuitin Clear patches

Keep out of the reach and sight of children.

Do not use this medicine after the 'EXP' date shown on the pack. Keep all patches in the carton, in their protective sachet, until you are ready to use one.

Do not use patches that are in sachets which are damaged or open.

6. Further information

Active ingredient

NiQuitin Clear 21 mg patches contain 114 mg Nicotine and deliver 21 mg of Nicotine over 24 hours.

NiQuitin Clear 14 mg patches contain 78 mg Nicotine and deliver 14 mg of Nicotine over 24 hours.

NiQuitin Clear 7 mg patches contain 36 mg Nicotine and deliver 7 mg of Nicotine over 24 hours.

Other ingredients

Ethylene/vinyl acetate copolymer, polyethylene terephthalate, polyethylene film, polyisobutylene and printing ink.

Each step (strength) of NiQuitin Clear patches comes in its own pack and each pack contains 7 patches (1 week kit) in individual sachets. A 14 patch pack (2 week kit) is available for step 1.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is Catalent UK Packaging Limited, Sedge Close, Great Oakley, Corby, Northamptonshire, NN18 8HS.

This leaflet was last revised in April 2009.

If you have any questions or comments about NiQuitin Clear, please FREEPHONE our Information Line on 0500 100 222.

NiQuitin is a registered trade mark of the GlaxoSmithKline group of companies.

