Leaflet Recto

NiQuitin® 21 mg transdermal patches
NiQuitin® 14 mg transdermal patches
NiQuitin® 7 mg transdermal 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 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).

In this leaflet:

1. **What NiQuitin Patches do**
2. **Check before you use NiQuitin Patches**
3. **How to use NiQuitin Patches**
4. **Possible side-effects**
5. **How to store NiQuitin Patches**
6. **Further information**

1. What NiQuitin Patches do

NiQuitin Patches are used to help people stop smoking. They work by replacing some of the nicotine you get from cigarettes. This type of treatment is called **Nicotine Replacement Therapy (NRT).**

The nicotine in cigarettes makes them addictive, but other substances in cigarette smoke, such as tar, carbon dioxide and other toxins, are more harmful to your health. **NRT products like NiQuitin Patches do not have the health dangers of tobacco**.

The nicotine from NRT reduces your cravings for cigarettes and helps you resist the urge to smoke. It also relieves some of the unpleasant symptoms (like feeling ill or irritable) that smokers have when they try to give up. The patches provide a steady amount of nicotine to your body, generally at a lower level than from cigarettes.

NiQuitin Patches can be used to help you:
- stop smoking straightaway (*a quit attempt*).
- cut down on smoking, perhaps before you go on to stop completely (*reducing to quit or just reducing*).

In addition, NiQuitin Patches may be used when you:
- do not wish to smoke, for example in confined spaces (in the car, in the house), where others (such as children) could be harmed by tobacco smoke or in places where smoking is prohibited (temporary abstinence).
- develop cravings once you have stopped smoking.

Reducing the number of cigarettes smoked can increase he chances that you will go on to quit completely.

NiQuitin Patches can be used during pregnancy and breast-feeding (*see Pregnancy and breast-feeding* below).

Some people worry that, when they have stopped smoking, they may become dependent on NRT instead. This is very rare, and if it were to happen it is still safer than continuing to smoke. It is also an easier habit to break.

It is always better to stop smoking completely. Smoking is harmful and has no health benefits. NRT products like NiQuitin Patches can help you stop. Any risks or possible side-effects of nicotine from NRT are much less than the proven dangers of continuing to smoke.

Your chance of stopping smoking will be improved if you also take part in a support programme. These 'Stop Smoking' programmes are known as behavioural support. For more information:
- call the NHS Free Smoking Helpline on **0800 022 4332**, or visit **http://www.smokefree.nhs.uk** [or the Irish National Smokers Quitline on **1850 201 203**].
- or visit **http://www.niquitin.co.uk/** for information about a free online support plan.

2. Check before you use NiQuitin Patches

Do not use NiQuitin 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.
- if you have never been a regular smoker.
- if you are aged under 12. The level of nicotine in NRT is not suitable for children under 12. Children are more susceptible to the effects of nicotine, and it could cause severe toxicity, which can be fatal.

Take special care with NiQuitin Patches

Get help and advice from a healthcare professional:
- if you are in **hospital** because you have **heart disease**, have had a **heart attack**, severe **heart rhythm disturbances** or a **stroke**. Try to stop smoking without NRT unless your doctor has told you to use it. Once you are discharged from hospital, you can use NRT as normal.
- if you have **diabetes**. When you start using NRT, you need to monitor your blood sugar levels more often than usual, because your dose of medication for diabetes may need to be adjusted.
- 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 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.
- if you have **allergic eczema** or **dermatitis** you may get a reaction to the patch.
- if you have stomach or duodenal ulcers or an inflamed oesophagus or gullet (the passage between the mouth and stomach) because nicotine replacement therapy can make your symptoms worse.
- before using if you have ever experienced seizures (fits).
- if you have any concerns about becoming dependent or think you have become dependent on this product.

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 healthcare professional.

Pregnancy and breast-feeding

If you are pregnant or planning to become pregnant

Smoking when you are pregnant is harmful to the baby. The risks include poor growth before birth, damage to the baby's lungs, premature birth and stillbirth. Stopping smoking is the best way to improve your health and the health of your baby, and the earlier you stop smoking the better.

It is best to give up smoking without using NRT. If that's too difficult, using NRT is safer for you and your baby than continuing to smoke. The nicotine in NRT is less dangerous than the more harmful substances in cigarette smoke, such as tar and other toxins.

If you have tried to stop smoking without using NRT, and haven't been able to, your healthcare advisor may recommend NRT to help you stop. If you do use NRT during pregnancy:
- Start as early in your pregnancy as possible.
- Aim if possible to use NRT for only 2 to 3 months. But remember —the most important thing is not to smoke. It is safer to carry on using NRT than to start smoking again.
- If you can use them, NRT gum or lozenges are better than patches. That's because you will not be absorbing nicotine into your body all the time. But if you feel sick, you may need to use NRT patches instead.
- If you do need to use NRT patches, remove the patch before you go to bed.

If you are breast-feeding

Tobacco smoke is harmful to babies and children, causing breathing difficulties and other problems.

If you are breast-feeding, it is best if you stop smoking without using NRT. But if you do need to use NRT, the nicotine that gets into breast milk is less dangerous to your baby than breathing in second-hand smoke. If you do use NRT while breast-feeding:
- It is better to use NRT gum or lozenges to control your cravings as they happen, rather than patches. With gum or lozenges, you will not be absorbing nicotine into your body all the time.
- Try to breast-feed just before you take the gum or lozenge, when the nicotine levels in your body are at their lowest. That way, your baby gets as little nicotine as possible.

Driving and using machines

There are no known effects of NiQuitin Patches on your ability to drive or use machines. However, users of nicotine replacement products should be aware that giving up smoking can cause behavioural changes that could affect you.

3. How to use NiQuitin Patches

Adults and young people aged 12 years and over:

Instructions for use of NiQuitin Patches depend on whether you are:
- stopping smoking straightaway.
- cutting down on smoking before you stop.
- cutting down with no immediate plans to stop.
- going without cigarettes for a short time.

or if you have cravings after you have stopped smoking.

If you are under 18 years old and not ready to stop smoking straightaway, talk to a healthcare professional for advice.
In all cases:
- Apply the patches as described in the instructions below.
- Do not use more than the recommended dose.

NiQuitin Patches are not suitable for children under 12 years of age or for non- smokers. They may develop signs of nicotine overdose, including headache, sickness, stomach pain and diarrhoea.

Stopping smoking straightaway

Adults and young people aged 12 years and over:
It is important to make every effort to stop smoking completely. But if you do sometimes smoke a cigarette while using NRT, don't be discouraged — just keep going with your quit attempt. It may help to talk to a healthcare professional if you are finding your quit attempt difficult.

If you smoke 10 or more cigarettes a day, start with Step 1 and use the following step down programme:
Step 1, NiQuitin 21 mg for 6 weeks
Step 2, NiQuitin 14 mg for 2 weeks
Step 3, NiQuitin 7 mg for 2 weeks

If you smoke fewer than 10 cigarettes a day, then start with Step 2 and use the following step down programme:
Step 2, NiQuitin 14 mg for 6 weeks
Step 3, NiQuitin 7 mg for 2 weeks

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 end of Section 1 for more details.

Cutting down on smoking before you stop

Adults aged 18 years and over:
You may find it easier to quit completely later if you use NiQuitin Patches to help you cut down on smoking first.

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PharmaCode:	5576
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Manufacturing Site:	LTS Lohmann
Printer:	...
No. of Colours:	1

Process Black Cutter Guide

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Minimum font size: 8pt
Leading: 8.5pt
85% Horizontal Scaling

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If you smoke 10 or more cigarettes a day you can use NiQuitin Patches to help you prepare to stop smoking. You can continue to smoke for the first two to four weeks of using the patches, then stop smoking completely. You should use the following step down programme:

Pre-Step, NiQuitin 21 mg Patch + smoking for 2 - 4 weeks
STOP SMOKING COMPLETELY
Step 1, NiQuitin 21 mg for 6 weeks
Step 2, NiQuitin 14 mg for 2 weeks
Step 3, NiQuitin 7 mg for 2 weeks

If you have not felt able to make a quit attempt 6 weeks after starting to use NRT, you may find it helpful to talk to a healthcare professional.

✓ Cutting down with no immediate plans to stop

Adults aged 18 years and over:
It is always best to stop smoking completely, but using NRT to cut down is less harmful than continuing to smoke heavily. Cutting down the number of cigarettes you smoke each day will make it easier to quit completely in future.

If you feel an urge to smoke, apply a patch as directed in this leaflet to help you manage your cravings. Cut down the number of cigarettes you smoke per day by as many as possible.

It is best to stop smoking completely as soon as you feel able to. Follow the instructions above, under 'Stopping smoking straightaway'.

✓ Going without cigarettes for a short time

Adults aged 18 years and over:
NiQuitin Patches can help you manage your cravings so that you can resist cigarettes in situations where smoking is inappropriate, for example:
- where your second-hand smoke may damage other people, such as children.
- where smoking is not allowed, such as on a flight or in a hospital.
- when smoking should be avoided, such as before surgery.

If you feel an urge to smoke, apply a patch as directed in this leaflet. Continue to use patches during the period when you are avoiding smoking. Remove the patch when you start smoking again.

It is best to stop smoking completely as soon as you feel able to. Follow the instructions above, under 'Stopping smoking straightaway'.

Once you have stopped smoking...

After you have stopped smoking, you may still sometimes feel a craving for a cigarette. You can use NiQuitin Patches again to help you relieve these cravings — **using NRT is always better than smoking again**.

If you are worried that you may start smoking again, talk to a healthcare professional. They can advise you on how to get the best results from further courses of NRT.

If you are finding it difficult to stop using NRT completely, talk to a healthcare professional.

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. Do not apply to 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. The patch should be applied immediately after opening the sachet.
- 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 onto 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 and at about the same time each 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 or in a piece of aluminium foil.
- Throw the sachet containing the used patch away carefully, making sure it is out of the reach of children or pets.

NiQuitin 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 you remember then go on as before.

! If you use more NiQuitin Patches than you should

If a child has stuck a patch on themselves or eaten one, contact your doctor or hospital emergency department immediately.
If possible, show them the NiQuitin Patches packet or this leaflet. Symptoms of nicotine overdose in children include headache, sickness, stomach pain and diarrhoea.

If you apply too many patches, you may start to feel sick, dizzy and unwell. Remove all patches and contact your doctor or hospital emergency department immediately.

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. At the recommended doses **NiQuitin Patches** have not been found to cause any serious side-effects.

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.
- Very rare: Severe allergic reactions symptoms which include sudden wheeziness or tightness of the chest, rash and feeling faint.

Stop using the patch and tell a healthcare professional if you get these.
- 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 pains, 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.
- Sensitivity of the skin to sunlight.
- Seizures (fits), stop using this medicine if you experience seizures.

Tell a healthcare professional if you get any of these.

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not mentioned in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

If you smoke too much while using the patches
If you are following the programme for preparing to stop smoking, or cutting down with no immediate plans to stop, and you smoke too many cigarettes while you are wearing a patch, you may feel sick, dizzy and unwell. Stop smoking and remove the patch. Wash and dry the skin with water only (no soap) and contact your doctor, a pharmacist or nurse.

5. How to store NiQuitin Patches

- Keep out of the reach and sight of children.
- Do not use this medicine after the 'EXP' date shown on the sachet and outer packaging. The expiry date refers to the last day of the month.
- Store below 30°C.
- Keep all patches in the original 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.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What NiQuitin Patches contain

The active substance is nicotine. The 21 mg patches contain 114 mg of nicotine and deliver 21 mg over 24 hours. The 14 mg patches contain 78 mg of nicotine and deliver 14 mg over 24 hours. The 7 mg patches contain 36 mg of nicotine and deliver 7 mg over 24 hours.
The other ingredients are ethylene/vinyl acetate copolymer, polyethylene/aluminium/polyethylene terephthalate, polyethylene film, polyisobutylene and printing ink.

What NiQuitin Patches look like and the contents of the pack

Each step (strength) 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 (21 mg).

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is Omega Pharma Ltd, Wrafton, Braunton, Devon, EX33 2DL, UK and all enquiries should be sent to this address.

The manufacturer of **NiQuitin Patches** is

Lohmann Therapie-Systeme AG, Lohmannstrasse 2, 56626 Andernach, Germany.

This leaflet was last revised in July 2022.

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