

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# NiQuitin<sup>®</sup> Clear 21 mg Patch (nicotine)

MPT1673L1

**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).
- The name of your medicine is NiQuitin Clear 21 mg Patch, but it will be referred to as NiQuitin Clear Patches throughout the remainder of this leaflet.
- This medicine also available in other strengths.

**In this leaflet:**

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

### 1. WHAT NIQUITIN CLEAR PATCHES DO

**NiQuitin Clear Patches are used to help people stop smoking and quit vaping devices (e-cigarette/heat-not-burn tobacco/heated tobacco). This type of treatment is called Nicotine Replacement Therapy (NRT).**

Nicotine is a highly addictive substance that is present in cigarettes and vaping device products (e-cigarettes/heat-not-burn tobacco/heated tobacco).

In cigarette smoke, there are other substances, such as tar, carbon monoxide and other toxins, which are more harmful to your health. **NRT products like NiQuitin Clear Patches do not have the health dangers of tobacco.**

Other ways of consuming nicotine e.g. vaping (e-cigarettes/heat-not-burn tobacco/heated tobacco) are difficult to control and can lead to excessive consumption and addiction to nicotine. **NRT products like NiQuitin Clear Patches are medicines that contain precise amounts of nicotine and allow you to regulate, reduce and quit nicotine.**

The nicotine from NRT reduces your cravings for cigarettes or vapes and helps you resist the urge to use them. It also relieves some of the unpleasant symptoms (like feeling ill or irritable) that smokers or vapers 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 or vaping (e-cigarettes/heat-not-burn tobacco/heated tobacco), to help with cravings and other symptoms of nicotine addiction.

Some people worry that after stopping smoking, they may become dependent on NRT instead. This is very rare, and if it did happen, it is less harmful than with continuing to consume high levels of nicotine through smoking. It is also an easier habit to break.

It is always best to stop smoking or vaping completely. NiQuitin Clear Patches can be used to help you stop straightaway (*a quit attempt*).

However, NiQuitin Clear Patches can also be used to cut down on smoking or vaping, perhaps before you go on to stop completely (reducing to quit or just reducing).

In addition, NiQuitin Clear Patches may be used:

- When you do not wish or are unable to smoke or vape for example in confined spaces (in the car, in the house), where others (such as children) could be harmed by tobacco smoke or vape vapor, or in places where smoking or vaping is prohibited (*temporary abstinence*).
- In combination with an oral form of NiQuitin, if you have difficulty controlling your cravings (see section 3: How to use NiQuitin Clear Patches). It is more effective than using patches alone.
- When you develop cravings once you have stopped smoking or vaping. Reducing your nicotine intake can increase the chances that you will go on to quit completely.

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

**It is always better to stop smoking or vaping completely.**

Cigarettes and other tobacco products are especially harmful, and nicotine has no health benefits. Using NRT products like NiQuitin Clear Patches can help you stop. In general, any risks or possible side-effects associated with NRT are far outweighed by the proven dangers of continuing to smoke.

**If you are smoking cigarettes, 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 CLEAR PATCHES

**X 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).
- **you are an occasional or non-smoker or non-vaper.**
- 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 Clear 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 or vaping 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 tumor** (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 or vaping 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 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 Clear Patches on your ability to drive or use machines. However, users of nicotine replacement products should be aware that giving up smoking or vaping can cause behavioural changes that could affect you.

### 3. HOW TO USE NIQUITIN CLEAR PATCHES

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

Instructions for use of NiQuitin Clear Patches depend on whether you are:

- stopping smoking or vaping straightaway
- cutting down on smoking or vaping before you stop
- cutting down with no immediate plans to stop
- going without cigarettes or vapes (e-cigarettes/heat-not-burn tobacco/heated tobacco) for a short time or if you have cravings after you have stopped smoking or vaping.

If you have difficulty controlling your cravings, NiQuitin Clear Patches may also be used in combination with oral forms of NiQuitin, as it is more effective than using patches alone.

**If you are under 18 years old** and not ready to stop smoking or vaping 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 Clear Patches are not suitable for children under 12 years of age or for non-smokers and non-vapers.** They may develop signs of nicotine overdose, including headache, sickness, stomach pain and diarrhoea.

**✓ Stopping smoking or vaping devices (e-cigarettes/heat-not-burn tobacco/heated tobacco) straightaway**

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

It is important to make every effort to stop smoking or vaping completely. But if you do sometimes smoke a cigarette or vape 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**  
**If you use vaping liquid strengths above 6 mg/ml (0.6%)** start with Step 1 and use the following step-down programme.

**Step 1,** NiQuitin Clear 21 mg for 6 weeks

**Step 2,** NiQuitin Clear 14 mg for 2 weeks

**Step 3,** NiQuitin Clear 7 mg for 2 weeks

**👉 If you smoke fewer than 10 cigarettes a day,**  
**If you use vaping liquid strengths below 6 mg/ml (0.6%)** then start with Step 2 and use the following step-down programme.

**Step 2,** NiQuitin Clear 14 mg for 6 weeks

**Step 3,** NiQuitin Clear 7 mg for 2 weeks

As your body adjusts to not smoking or not vaping 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.

**✓ Gradual cessation: if you are unwilling or unable to quit smoking or vaping devices (e-cigarettes/heat-not-burn tobacco/heated tobacco) abruptly**

**Adults aged 18 years and over:**

You may find it easier to quit completely later if you use NiQuitin Clear Patches to help you cut down on your use of smoking or vaping first.

**👉 If you smoke 10 or more cigarettes a day**  
**If you use vaping liquid strengths above 6 mg/ml (0.6%)** you can use NiQuitin Clear patches to help you prepare to stop. You can continue to smoke or vape for the first two to four weeks of using the patches, then stop using it completely. You should use the following step-down programme:

**Pre-Step,** NiQuitin Clear 21 mg + smoking or vaping for 2 - 4 weeks

**STOP SMOKING / VAPING COMPLETELY**

**Step 1,** NiQuitin Clear 21 mg for 6 weeks

**Step 2,** NiQuitin Clear 14 mg for 2 weeks

**Step 3,** NiQuitin Clear 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.

**✓ Smoking or vaping device (e-cigarettes/heat-not-burn tobacco/heated tobacco) reduction: cutting down with no immediate plans to stop**

**Adults aged 18 years and over:**

**It is always best to stop smoking or vaping completely,** but using NRT to cut down is less harmful than continuing smoking heavily. Cutting down the amount of smoking or vaping each day, will make it easier to quit completely in the future.

If you feel an urge to smoke or vape, apply a patch as directed in this leaflet to help you manage your cravings. Cut down the amount of cigarettes, vapes (e-cigarettes/ heat-not-burn tobacco/ heated tobacco) you use per day by as many as possible.

**It is best to stop smoking or vaping completely as soon as you feel able to. Follow the instructions above, under 'Stopping smoking or vaping devices (e-cigarettes/heat-not-burn tobacco/ heated tobacco) straightaway'.**

**✓ Going without cigarettes, vaping devices (e-cigarettes/heat-not-burn tobacco/heated tobacco) for a short time**

**Adults aged 18 years and over:**

NiQuitin Clear Patches can help you manage your cravings so that you can resist in situations where smoking or vaping is inappropriate, for example:

- where your second-hand smoke or vapor may damage other people, such as children
- where smoking or vaping are not allowed, such as on a flight or in a hospital
- when smoking or vaping should be avoided, such as before surgery.
- If you feel an urge to smoke or vape, apply a patch as directed in this leaflet.

Continue to use patches during the period when you are avoiding smoking/vaping use. Remove the patch when you start again.

**It is best to stop smoking or vaping, completely** as soon as you feel able to. Follow the instructions above, under '*Stopping smoking or vaping devices (e-cigarettes/heat-not-burn tobacco/ heated tobacco) straightaway*'.

**Combination therapy with oral forms of NiQuitin**

If you feel cravings for smoking or vaping, the combination therapy of NiQuitin Clear Patches and an oral form of NiQuitin will give you a better chance to quit than the patches alone.

In combination with your patch, take a NiQuitin lozenge/mini lozenge, or as soon as you feel a sudden nicotine craving – an average of 5-6 pieces per day is recommended. Do not take more than 15 NiQuitin 2mg lozenges/mini lozenges/chewing gums per 24 hours. If you use NiQuitin 4 mg mini lozenges/lozenges, you should not take more than 10 pieces per 24 hours.

Continue using NiQuitin lozenges/mini lozenges for 2-3 months. As soon as you feel less nicotine cravings, start to reduce the dosage gradually. When daily use is reduced to 1-2 doses, treatment should be discontinued.

If you smoke more than 10 cigarettes per day If you use vaping liquid strengths above 6 mg/ml (0.6%)		
Duration	Patches	NiQuitin2mg or 4mg lozenges
Step 1: 6 weeks	NiQuitin Clear 21 mg/24 h	5-6 pieces per day*
Step 2: 2 weeks	NiQuitin Clear 14 mg/24 h	Continue using lozenges/mini lozenges when necessary*
Step 3: 2 weeks	NiQuitin Clear 7 mg/24 h	
After 8-10 weeks	Stop using NiQuitin Clear Patches	Reduce the number of lozenges/mini lozenges gradually. When daily use is reduced to 1-2 pieces, treatment should be discontinued.

\* 4 mg oral dose for the first 6 weeks if you smoke more than 20 cigarettes per day. Then switch to a weaker oral dose. Do not use more than 10 pieces of NiQuitin 4 mg lozenges/mini lozenges per 24 hours. When switching to a weaker oral dose, do not use more than 15 pieces of NiQuitin 2 mg lozenges/mini lozenges per 24 hours.

If you are a light smoker (you smoke less than 10 cigarettes a day) If you use vaping liquid strengths below 6mg/ml (0.6%)		
Duration	Patches	NiQuitin 2mg lozenges
Step 1: 6 weeks	NiQuitin Clear 14 mg/24 hr	5-6 pieces per day**
Step 2: 2 weeks	NiQuitin Clear 7 mg/24 hr	Continue using lozenges/mini lozenges when necessary**
After 8-10 weeks	Stop using NiQuitin Clear Patches	Reduce the number of lozenges/mini lozenges gradually. When daily use is reduced to 1-2 pieces, treatment should be discontinued.

\*\* Do not use more than 15 pieces of NiQuitin 2 mg lozenges/mini lozenges per 24 hours.

#### Once you have stopped smoking or vaping...

After you have stopped smoking or vaping, you may still sometimes feel a craving for nicotine. You can use NiQuitin Clear 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 or vaping 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 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.

NiQuitin Clear is intended for 24-hour use but if you prefer, the patch can be removed before you go to bed (after 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 or vape felt by some nicotine users 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 more NiQuitin Clear 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 Clear 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 or vapes, and are more likely the more nicotine you take, but not everybody gets them. At the recommended doses **NiQuitin Clear Patches** have not been found to cause any serious side-effects.

Stopping smoking or vaping 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 reaction symptoms which include sudden wheeziness or tightness of the chest, rash & 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 these:

- Abnormal dreams, trembling, palpitations (feeling your heartbeat).
- 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 smoke or vape too much while using the patches

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

#### Reporting of side effects

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 via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. HOW TO STORE NIQUITIN CLEAR PATCHES

- Keep out of sight and reach 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.
- Do not store above 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.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- 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 Clear Patches contain

The active substance is nicotine. Each patch contains 114 mg nicotine and delivers 21 mg nicotine in 24 hours by application to the skin.

Also contains ethylene/vinyl acetate copolymer, polyethylene terephthalate, polyethylene film, polyisobutylene and silicone-coated polyester film.

#### What NiQuitin Clear Patches look like and the contents of the pack

Each patch is rectangular and is comprised of clear backing and a protective liner. The patch is embossed with NCQ 21.

Each pack contains 7 patches (1 week kit) or 14 patches (2 weeks kit) in individual sachets.

Manufactured by LTS Lohmann Therapie-Systeme AG, Lohmannstr.2, Andernach, Rheinland-Pfalz, 56626, Germany.

Famar A.V.E Anthoussa Plant, Anthoussa Avenue 7, Anthoussa Attiki, 15344, Greece.

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