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NiQuitin Pre-Quit Clear 21mg Patch

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 Pre-Quit 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).

In this leaflet:

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

1. What NiQuitin Pre-Quit Clear Patches do

NiQuitin Pre-Quit Clear 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)**. They are for smokers who smoke more than 10 cigarettes a day.

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 Pre-Quit Clear Patches do not have the health dangers of tobacco.**

It is always better to stop smoking straightaway. However if you are not able to, you can use NiQuitin Pre-Quit Clear Patches as a first step towards stopping completely. The nicotine from NRT reduces your cravings for cigarettes and helps you resist the urge to smoke. The patches provide a steady amount of nicotine to your body, generally at a lower level than from cigarettes.

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

NiQuitin Pre-Quit Clear 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 Pre-Quit Clear 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 Pre-Quit Clear Patches

Do not use NiQuitin Pre-Quit 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**
- if you are an occasional smoker
- if you are **aged under 18**.

Take special care with NiQuitin Pre-Quit 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 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.

- before using if you have ever experienced seizures (fits).

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 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.

3. How to use NiQuitin Pre-Quit Clear Patches

Pre-Quit Programme

Adults aged 18 years and over:

For 2 - 4 weeks, apply one patch once a day and continue to smoke as needed. Once you have completed the NiQuitin Pre-Quit programme, you should stop smoking completely and move on to the NiQuitin step down patch programme. The following table is a guide:

Pre-Quit, NiQuitin Pre-Quit Clear 21 mg patch + smoking for up to 2 - 4 weeks

STOP SMOKING 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

Talk to a healthcare professional if:

- you have not been able to cut down the number of cigarettes you smoke each day after 4 weeks of using the patches.

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.

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- 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.

- After 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.

- Throw the sachet containing the used patch away carefully, making sure it is out of the reach of children or pets.

NiQuitin Pre-Quit 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 Pre-Quit Clear patch 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 felt by 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 more NiQuitin Pre-Quit 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 Pre-Quit 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, and are more likely the more nicotine you take, but not everybody gets them. At the recommended doses **NiQuitin Pre-Quit Clear 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.

Side-effects may occur with certain frequencies, which are defined as follows:

Very common: affects more than 1 user in 10

Common: affects 1 to 10 users in 100

Uncommon: affects 1 to 10 users in 1,000

Rare: affects 1 to 10 users in 10,000

Very rare: affects less than 1 user in 10,000

Not known: frequency cannot be estimated from the available data.

Side-effects at the application site

- Severe reactions at the application site which may include severe redness of the skin, itchiness and swelling (uncommon).
Stop using the patch and tell a healthcare professional if you experience this.

- Slight redness and itching, burning and tingling of the skin where the patch has been. This usually disappears within a day (very common)
- Pain around the application site (common)
- Skin reactions (e.g. allergic dermatitis, contact dermatitis) (very rare)

Other side-effects

If you notice the following very rare but serious side-effect, stop using the patch and tell a healthcare professional:

- Severe allergic reaction symptoms which include sudden wheeziness or tightness of the chest, rash and feeling faint

Very common side-effects

- Headache, dizziness
- Abnormal dreams, difficulty in sleeping
- Feeling or being sick

Common side-effects

- Nervousness
- Trembling
- Palpitations (feeling your heart beat)
- Indigestion, stomach pains, diarrhoea, dry mouth or constipation
- Increased sweating
- Tiredness or weakness
- Shortness of breath, cough or sore throat
- Joint or muscle pain

Uncommon side-effects

- Feeling unwell, flu-like symptoms
- Increased heart rate

Very rare side-effects

- Sensitivity of the skin to sunlight

If you experience **seizures** (fits), **stop** using this medicine.

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.

If you **smoke too much while using the patches**

If 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.

5. How to store NiQuitin Pre-Quit Clear 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 Pre-Quit Clear Patches contain

The **active substance** is nicotine. The patches contain 114 mg of nicotine and deliver 21 mg over 24 hours.

The **other ingredients** are ethylene/vinyl acetate copolymer, polyethylene terephthalate, polyethylene film, polyisobutylene and printing ink.

What NiQuitin Pre-Quit Clear Patches look like and the contents of the pack

Each pack contains 7 patches (1 week kit) in individual sachets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is Omega Pharma Ltd, 32 Vauxhall Bridge Road, London, SW1V 2SA, UK and all enquiries should be sent to this address.

The manufacturer of **NiQuitin Pre-Quit Clear Patches** is FAMAR A.V.E. AVLON PLANT (48°), 48° km National Road Athens - Lamia, Avlona Attiki, 19011, Greece.

NiQuitin and **Pre-Quit** are trade marks of ELAN PHARMA INTERNATIONAL LTD.

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