

Package leaflet: Information for the user

NiQuitin[®]

7mg, 14mg, 21mg/24hrs
transdermal patches

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 healthcare professional has told you.

- Keep this leaflet. You may need to read it again.
- Ask a healthcare professional (e.g. doctor, nurse, smoking cessation adviser or pharmacist) if you need more information or advice.
- If you get any side effects talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.
- Throughout this leaflet **NiQuitin** transdermal patches are referred to as **NiQuitin**.

What is in this leaflet

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

1. What NiQuitin is and what it is used for

NiQuitin are **skin patches that deliver nicotine to help people stop smoking**. This type of treatment is called Nicotine Replacement Therapy (or NRT for short). NiQuitin patches come in three strengths: 21mg, 14mg and 7mg/24hrs. People wanting to quit smoking **start on a stronger patch and gradually switch to weaker ones (see Section 3: How to use NiQuitin)**. Each strength comes in its own pack.

It is the nicotine in cigarettes that can make you addicted to them. NiQuitin helps you give up smoking by replacing some of the nicotine you get from cigarettes. Each patch slowly releases nicotine into the body. This relieves some of the unpleasant symptoms that smokers may get when they try to quit, relieves cravings for a cigarette and helps to resist the urge to smoke.

NiQuitin **patches may be used together with any oral NiQuitin** (lozenge, mini lozenge or gum) if you have relapsed after trying to quit with NRT, when one NiQuitin product is not enough to control your cravings, or if you are a heavy smoker (e.g. more than 10 cigarettes per day) (see Section 3: How to use NiQuitin). NRT does not have the health dangers of tobacco - it does not contain the tar, carbon monoxide or other toxins in cigarette smoke. Some people worry that they may become dependent on the nicotine in NRT instead. This is very rare but, if it did happen, it is less harmful than continuing to smoke. It is also an easier habit to break.

Your chances of quitting will be improved if you take part in a **support programme**. For information on these, please talk to a healthcare professional. You can also call the National Smoker's Helpline on 1800 201 203 or visit www.quit.ie.

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

2. What you need to know before you use NiQuitin

Do not use NiQuitin:

- 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, an occasional smoker or under the age of 12 years.

Warnings and precautions

Talk to your healthcare professional before using NiQuitin:

- if you are in **hospital because of a heart attack, severe heart rhythm problems or a stroke**. You should try to quit smoking without nicotine replacement therapy (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. Your insulin or medicine requirements may change.
- if you have had **allergic reactions** that involve swelling of the lips, face and throat or itchy skin rash. 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 a history of **epilepsy (fits)**.
- if you have **stomach or duodenal ulcers** or an inflamed oesophagus (the passage between the mouth and stomach). NRT can make symptoms worse.
- if you have a history of **cardiovascular disease** (such as **heart disease, angina or high blood pressure**) and wish to use NiQuitin patches in combination with NiQuitin lozenges, mini-lozenges or gums.
- if you have serious **liver or kidney problems**. You may be more likely to get side effects.
- if you have uncontrolled, **overactive thyroid gland** or **phaeochromocytoma** (a tumour of the adrenal gland that can affect blood pressure). Nicotine may make your symptoms worse.
- if you have concerns about becoming dependent or think you have become dependent on this product.

Talk to your healthcare professional before using NiQuitin if any of these apply to you.

Children (under 12 years)

The levels of nicotine in NRT are not suitable for children under 12. Nicotine affects children more than adults. It could cause severe poisoning in children which can cause death.

Other medicines and NiQuitin

Tell your healthcare professional if you are taking, have recently taken or might take any 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

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

Ideally, if you are pregnant, you should stop smoking without using nicotine replacement therapy (NRT). However, if you have tried and this has not worked, **Nicotine Replacement Therapy may be recommended by a healthcare professional**. This is because it is better for your baby than if you carry on smoking. You should use NRT as early as possible in your pregnancy and ideally for only 2-3 months. Remember, the most important thing is to stop smoking. Oral NRT such as lozenges may be preferable to patches, because you do not get the nicotine continuously. However, patches may be better if you have nausea or sickness.

If you are **breast-feeding** tobacco smoke causes breathing difficulties and other problems in babies and children. You should try to quit first without using NRT. If you need NRT to quit, the amount of nicotine your baby may get is small, but this is still less harmful to them than breathing in smoke. Products such as lozenges may be preferable to patches because you do not get the nicotine continuously. It is also better to breast-feed just before you take NRT so that your baby gets as little nicotine as possible.

Do not use NiQuitin patches in combination with NiQuitin lozenges, mini lozenges or gum if you are pregnant or breast-feeding unless a healthcare professional considers it necessary. This is because this combination has not been tested in women who are pregnant or breast-feeding.

Driving and using machines

There are no known effects of NiQuitin patches on your ability to drive and use machines. However, quitting smoking can cause behavioural changes that could affect you in this way.

3. How to use NiQuitin

Always use this medicine exactly as described in this leaflet or as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

As your body adjusts to not smoking, **reduce the strength of patches until you no longer need them**. This step down programme allows you to gradually overcome your body's need for nicotine. To increase your chances of success, it is important you complete the step down programme in full.

Apply a new patch every day. The patch should be used only once, for up to 24 hours. Do not use more than the recommended dose.

Patch for adult smokers (18 years and over)

Table 1: Heavy smokers (more than 10 cigarettes a day)

For first 6 weeks	Step 1, 21 mg/24hrs patch every day
Weeks 7 and 8	Step 2, 14 mg/24hrs patch every day
Weeks 9 and 10	Step 3, 7 mg/24hrs patch every day
After 10 weeks	Patches can be continued if necessary*

Table 2: Light smokers (less than 10 cigarettes a day)

For first 6 weeks	Step 2, 14 mg/24hrs patch every day
Weeks 7 and 8	Step 3, 7 mg/24hrs patch every day
After 8 weeks	Patches can be continued if necessary*

***The patches can be continued beyond the recommended 8 or 10 weeks if you need them to stay off cigarettes. However, if you are still using them after 9 months, get advice from a healthcare professional.**

Talk to a healthcare professional if you are:

- worried that you might start smoking again
 - finding it too difficult to stop using the patches
- If you do start to smoke again, they can suggest how to get the best results from further courses of nicotine replacement therapy.

Use in children and adolescents

Adolescents (12-17 years) should follow the instructions in Table 1 and Table 2 but only use the patches for 12 weeks in total. If you feel the need to use NiQuitin for longer than 12 weeks, talk to a healthcare professional for advice. You should not use NiQuitin patches in combination with NiQuitin lozenges, mini-lozenges or gums. Do not exceed the stated dose.

Children under 12 years should not use NiQuitin.

Combining patches plus oral NiQuitin

NiQuitin patches are not always enough on their own. **Using oral NiQuitin at the same time as patches may help** to control sudden cravings and increase your chance of quitting than with patches alone.

Oral NiQuitin comes as lozenges, mini lozenges or gum.

Combining patches and oral NiQuitin may help:

- if you have relapsed after trying to quit with NRT
- if one NiQuitin product is not enough to control your cravings
- if you are a heavy smoker (e.g. you smoke 10 or more cigarettes per day)
- Only if you are 18 years or older and any of the above apply

Follow the same 'step' process with the patches, but take oral NiQuitin when you experience a sudden craving – around 5-6 pieces are recommended per day. See Tables 3 and 4 on the back of this leaflet for details.

When using patches and oral NiQuitin together:

- do not take more than 15 pieces of 1.5mg or 2mg

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oral NiQuitin in 24 hours
 > do not take more than 10 pieces of 4mg oral NiQuitin in 24 hours
 For more information, read the leaflet that comes with the oral NiQuitin.

Table 3: Combination therapy for heavy smokers (more than 10 cigarettes per day)

		Oral NiQuitin (gum, lozenge or mini lozenge)
For first 6 weeks	Step 1, 21 mg/24hrs patch every day	5 to 6 pieces of oral NiQuitin per day. Start on 4mg oral NiQuitin if you smoke more than 20 cigarettes a day
Weeks 7 and 8	Step 2, 14 mg/24hrs patch every day	Reduce to a lower strength oral NiQuitin and continue to use when necessary
Weeks 9 and 10	Step 3, 7 mg/24hrs patch every day	
After 10 weeks	Stop using patches when you can	Reduce the amount of oral NiQuitin gradually. When this is down to 1-2 pieces per day, stop treatment

Table 4: Combination therapy for light smokers (less than 10 cigarettes per day)

		Oral NiQuitin (gum, lozenge or mini lozenge)
For first 6 weeks	Step 2, 14 mg/24hrs patch every day	5 to 6 pieces of oral NiQuitin per day, 2mg or 1.5mg.
Weeks 7 and 8	Step 3, 7 mg/24hrs patch every day	Continue to use oral NiQuitin when necessary.
After 8 weeks	Stop using patches when you can	Reduce the amount of oral NiQuitin gradually. When this is down to 1-2 pieces per day, stop treatment.

How to apply your patches

Choose clean, dry hairless skin for the patch to make sure that it sticks properly. Avoid skin creases (such as over a joint), or where skin folds when you move. Also avoid skin which is red, broken or irritated.
 > Do not remove the patch from its sachet until you are ready to use it. Do not use if the seal is broken.
 > 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 liner.
 > Immediately apply the sticky side of the patch to your skin. Press the patch firmly with the palm of your hand for at least 10 seconds. Make sure it sticks well, especially around 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.

NiQuitin generally sticks well to most people's skin. However, a patch may occasionally come off. **If your patch falls off**, put on a new patch, making sure you choose a different skin site. You can then continue to change patches at your usual time.

How to change your patches

A new patch should be applied once a day and at about the same time each day, preferably soon after waking. Leave each patch in place for 24 hours. Always choose a different area of skin for each new patch. Do not reuse the same skin site for at least seven days.

Disposal of your patches

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 this away carefully, making sure it is out of the reach of children or pets.

If you wish, patches can be removed before you go to bed (after about 16 hours) and a new one put on when you wake up. However, removing it before bed will make it less effective at relieving the urge to smoke upon waking.

If you use more patches than you should

If you use too many patches at once you may start to feel sick, dizzy and unwell. Remove all patches and wash and dry the skin with water only (no soap). Get advice straightaway from a doctor or hospital casualty department. If possible show them the packet or this leaflet.

The patches are not suitable for children under 12 or non-smokers. If used by children or non-smokers, they may show signs of nicotine overdose, such as headache, sickness, stomach pains and diarrhoea.

If a child has stuck a patch on themselves or eaten one, remove any patches from the skin and wash with water only (no soap) then dry. Contact your doctor or nearest hospital casualty department straightaway. If possible show them the packet or this leaflet.

If you forget to use NiQuitin

If you forget to change your patch at the usual time, change it as soon as you remember. You can then continue to change patches at your usual time. Do not use two patches at the same time to make up for a forgotten dose.

If you stop using NiQuitin

If you stop using this medicine before the recommended time you may feel the urge to smoke again.
 If you have any further question on the use of this medicine, ask your healthcare professional.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.
 At the recommended doses, NiQuitin has not been found to cause any serious side effects.

Stopping smoking itself can cause some symptoms such as feeling weak, dizziness, headache, cough and flu-like symptoms.

Other symptoms may also be related to giving up smoking, such as changes in mood, insomnia, sleep disturbance, being unable to concentrate, or feeling depressed, irritable, anxious, drowsy, restless or nervous.

Very common (may affect more than 1 in 10 people):
 > skin reactions in the area where you apply the patch
 > sleep disturbances, including insomnia and abnormal dreams
 > feeling /being sick
 > headache
 > dizziness

Common (may affect up to 1 in 10 people):
 > nervousness
 > trembling
 > shortness of breath
 > sore or swollen throat, cough
 > indigestion, stomach pains, diarrhoea, constipation, dry mouth
 > sweating
 > joint, muscle, chest and limb pains
 > tiredness or weakness
 > palpitations (feeling your heart beat)

Uncommon (may affect up to 1 in 100 people):
 > allergic reaction
 > increased heart rate
 > flu-like symptoms

Very rare (may affect up to 1 in 10,000 people):
 > skin reactions, sensitivity of the skin to sunlight
 > severe allergic reaction - symptoms can include wheeziness or tightness of chest, rash and feeling faint.

Not known (frequency not known):
 > Seizures (fits)

You may get slight redness, itching, burning and tingling of the skin where a patch has been. This usually disappears quickly after removal of the patch. Rarely, a more severe reaction at the site may occur including redness, swelling or rash that does not go away after 4 days or a generalized skin reaction. This is more likely if you have a history of dermatitis. If this happens, stop using the patch and tell your doctor.

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 HPRAs Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NiQuitin

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

- > The active substance is nicotine.
- > The other ingredients are ethylene vinyl acetate copolymer, polyethylene/aluminium/polyethylene terephthalate layer, polyethylene film, polyisobutylene and printing ink.

What NiQuitin looks like and contents of the pack

NiQuitin is a matt, pinkish-tan, rectangular patch for sticking on your skin.

Each Step (strength) comes in its own pack and each pack contains 7 or 14 patches. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland and all enquiries should be sent to this address.

Manufacturer: LTS Lohmann Therapie-Systeme AG, Lohmannstrasse 2, 56626 Andernach, Germany. Famar A.V.E. Avlon Plant (48th), 48th km National Road Athens - Lamia, Avlona Attiki, 19011 Greece.

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

- Ireland:** NiQuitin 7mg/24hrs Transdermal Patch, NiQuitin 14mg/24hrs Transdermal Patch, NiQuitin 21mg/24hrs Transdermal Patch
- Italy:** NiQuitin 7mg/24 ore cerotti transdermici, NiQuitin 14mg/24 ore cerotti transdermici, NiQuitin 21mg/24 ore cerotti transdermici
- UK:** Nicabate 7mg/24hrs Transdermal Patches, Nicabate 14mg/24hrs Transdermal Patches, Nicabate 21mg/24hrs Transdermal Patches

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● Process Black ● Cutter

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